Evolution of ACO Initiatives at CMS: Letters and Email Messages

The comments in this collection of PDFs are in response to the Center for Medicare and Medicaid Innovation's Request for Information, "Evolution of ACO Initiatives at CMS". The CMS Innovation Center received these comments in the form of a letter or email message. Some organizations submitted their comments using the Wufoo online tool. The CMS Innovation Center displays those comments in the PDF entitled, "Evolution of ACO Initiatives at CMS: Wufoo Entries".

AMCP Academy of Managed Care Pharmacy®

February 28, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dr. Patrick Conway, MD
Deputy Administrator, Innovation & Quality and CMS Chief Medical Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
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RE: Request for Information: *Evolution of ACO Initiatives at CMS;* Section II.B, Integration of Part D Benefits

Dear Administrator Tavenner and Dr. Conway:

The Academy of Managed Care Pharmacy (AMCP) writes today in response to the Centers for Medicare and Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (CMMI) Request for Information (RFI): *Evolution of ACO Initiatives at CMS* released in December 2013. Specially, AMCP comments focus on the Section II.B. Integrating Accountability for Medicare Part D Expenditures. AMCP supports integration of both Medicare Part D plans into accountable care organizations (ACOs) and the use of pharmacists' medication management as an essential component of team-based care in ACOs.

Appropriate medication use is an important component of health care, and Medicare beneficiaries with chronic conditions fill approximately 50 prescriptions per year, account for more than three-quarters of all hospitalizations and are 100 times more likely than individuals without a chronic illness to be re-hospitalized.[1] These statistics demonstrate the important role of medications in the care of chronically ill Medicare beneficiaries, but also demonstrates the need for better integration among Medicare Part D plans and the pharmacists and pharmacies that help deliver medication management to ensure safe and appropriate use. Yet, neither Medicare Part D plans nor pharmacists' services are fully integrated in Medicare's ACO model, but should be, considering their critical and growing role in managing patient care.

However, full integration of Part D into ACOs requires CMS and CMMI and other stakeholders to take the following important and necessary steps:

- Recognize pharmacists and pharmacies as providers under the Medicare program to help improve health care outcomes and reduce costs;
- Incorporate pharmacists, pharmacies, and pharmacy benefit management companies (PBMs) in waivers from federal fraud and abuse laws for ACOs under the Medicare Shared Savings Programs to ensure that these entities and individuals may fully participate;
- Allow pharmacies to enter into risk-based contracts for services; and,
- Include pharmacists, pharmacies, and PBMs as full users of electronic health records (EHRs).

AMCP also encourages CMS and CMMI to examine the Medicare Advantage-Prescription Drug (MA-PD) program as examples of the successful integration of medications into a risk based model.

AMCP is a national professional association of pharmacists, physicians, nurses, and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's nearly 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by managed care pharmacy benefits.

Each of AMCP's recommendations will be examined below in greater depth.

Recognize Pharmacists and Pharmacies as Providers under Part B of the *Social Security Act* (SSA) or Support Recognition in ACO Section of SSA

AMCP Recommendation: CMS and CMMI should encourage Congress to recognize pharmacists and pharmacies under Medicare Part B of the SSA or as providers in ACOs to encourage their full participation and benefit from the important medication management services they provide.

AMCP Comments: Lack of recognition of pharmacists and pharmacies as Medicare providers presents an enormous challenge to full integration of Medicare Part D into ACOs, because these providers do not have the ability to receive payment under the Medicare program and more importantly, cannot fully participate in ACOs as currently adopted. The SSA[i] defines "physicians" under the Medicare program, as including doctors of medicine and osteopathy, doctors of dental surgery and dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors, but not pharmacists and pharmacies. This omission means that pharmacists and pharmacies currently may only receive payment based on dispensing medications and, in limited circumstances, may receive payment when performing under the direct supervision of a physician or other Medicare-authorized provider. AMCP continues to support the objective of achieving Medicare Part B provider status for pharmacists and urges CMS and CMMI to work with Congress to take action in this direction.

AMCP recognizes that full Medicare Part B recognition might not be attainable in the timeframe necessary to ensure that pharmacists make meaningful contributions to ACOs and other integrated delivery models. Therefore, AMCP urges Congress to consider the inclusion of pharmacists as providers in ACOs under Section 1899 of the SSA. In December 2013, AMCP joined other pharmacy organizations in support of an amendment to the 2013 *Sustainable Growth Rate* (SGR) legislation to incorporate pharmacists as health care providers in ACOs.[ii] While the amendment was not offered because of time constraints during debate, the amendment had support in the Senate Finance Committee and among other pharmacy groups. AMCP urges CMS and CMMI to encourage Congress to reconsider

adoption of this amendment under SGR or other legislation to expedite inclusion of pharmacists and pharmacies as providers in ACOs.

Pharmacists work in organizations across diverse care settings to provide medication management. The goal of medication management is to ensure safe, effective, appropriate, and economical use of prescription medications for patients using a patient-centered interdisciplinary, evidence-based approach.[iii] Examples of where ACOs could incorporate pharmacists' medication management services include:

- Medication reconciliation where pharmacists utilize clinical interventions and health information technology (HIT) solutions to establish complete, accurate, and updated medication records, particularly during transitions of care from one health setting to others. A 2013 systematic review of the use of medication reconciliation to reduce hospital readmissions showed that pharmacists' involvement in medication reconciliation plays a "major role" in successful interventions.[iv] Medication reconciliation is a critical component of ACOs' ability to achieve the necessary outcomes to reduce hospital readmissions, and therefore could benefit greatly from the inclusion of pharmacists.
- Medication therapy management clinics for anticoagulation; transplant programs; HIV; hepatitis; psychiatric and lipid management. Patients with chronic diseases requiring multiple medications are at high risk for hospitalization and could benefit from pharmacists' interventions that help to ensure safe, effective, and affordable medication use, while reducing and managing medication-related problems.

The pharmacists' services described above are targeted at many of the domains CMS has identified for improving outcomes in ACOs, including: care coordination/ patient safety with a measure using medication reconciliation after discharge from an inpatient facility; and better health for populations, including improving care for patients with diabetes, ischemic vascular disease, heart failure, and coronary artery disease.[v] AMCP's 2012 white paper, *Pharmacists as Vital Members of ACOs: Illustrating the Important Role Pharmacists Play on Health Care Teams*,[vi] provides specific examples of models that include pharmacists used by existing health systems. CMS and CMMI should consult this white paper as a resource for programs that incorporate pharmacists.

Incorporate Pharmacists, Pharmacies, and PBMs in Waivers from Federal Fraud and Abuse Laws for ACOs under the Medicare Shared Savings Programs

AMCP Recommendation: Amend or clarify federal fraud and abuse regulations to allow pharmacists, pharmacies, and PBMs to actively participate in ACOs by incorporating them into waivers that allow them to share directly in cost savings.

AMCP Comment: The *Affordable Care Act* implemented several waivers to laws related to civil monetary penalties (CMPs) for gainsharing, beneficiary inducement, and the federal Anti-Kickback statute[vii] that allows for certain health care providers and suppliers to share savings under ACO arrangements and other Medicare shared savings programs. To integrate Medicare Part D into ACOs, PBMs, pharmacists, and pharmacies would have to be full participants in the gainsharing waiver and other waivers afforded to certain health care providers and entities allowing them to share cost savings.

Allow Pharmacies to Enter into Risk Based Contracts for Services under Medicare Part D

AMCP Recommendation: Revise provisions in the Medicare Part D proposed rule[viii] that imply risk based contracting with pharmacies would be prohibited and that contract terms between Part D plans and pharmacies be limited to costs of drugs and dispensing.

AMCP Comment: AMCP's comments to the Medicare Part D proposed rule released in January 2014 will include an extensive analysis of this issue related to CMS' interpretation of the non-interference clause; preferred network prohibitions; and any willing provider provisions. AMCP believes that the provisions, as drafted, could limit future opportunities for Part D plans to engage pharmacies in ACO models by prohibiting risk-based payments or limiting contracts to payments for drugs and dispensing only. In light of CMS' proposed prohibition on engaging pharmacies in insurance risk contracts, the CMS Part D rule seems to contradict the overall goal of ACOs and other initiatives to lower costs and improve outcomes through performance-based services. CMS and CMMIs' consideration of this issue is particularly important as it evaluates the questions posed under Section II.A.1: Transition to greater insurance risk.

Including Pharmacies, Pharmacists, and PBMs as Full Users of EHRs

AMCP Recommendation: CMS and CMMI should work with the Office of the National Coordinator, the Department of Health and Human Services, Congress, and pharmacy and managed care pharmacy stakeholders to ensure that pharmacists, pharmacies, and PBMs have the ability to fully utilize EHRs to share and access medication records and comprehensive patient information.

AMCP Comment: The *American Recovery and Reinvestment Act of 2009* included provisions and resources to develop bi-directional EHRs for certain eligible providers, including physicians and hospitals, but not pharmacists and pharmacies.[ix] As a result, pharmacists do not have the ability to read full EHRs containing a patient's comprehensive information, add recommendations or other notations to EHRs, or fully share prescription records and other prescription information among and between eligible entities. This situation is a significant barrier to integration of Medicare Part D into ACOs, because proper health information technology infrastructure is a key to success.

Conclusion

AMCP thanks CMS and CMMI for considering public comments regarding potential integration of Medicare Part D into ACOs. AMCP believes that this step could help improve the goals of the program—improving patient outcomes while lowering costs—but certain critical steps must be taken before fully realizing that objective. AMCP looks forward to working with CMS and CMMI in moving this initiative forward. If we can answer any questions or provide additional information, please contact me at (703) 683-8416 x645 or erosato@amcp.org.

Sincerely,

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

[i] Section 1861(r) of the *Social Security Act.*

[ii] AMCP Letter to Senate Finance Committee Supporting Amendment to SGR to incorporate pharmacists as health care providers in ACOs. December 11, 2013. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=17437. Accessed February 27, 2014.

[iii] Pharmacists as Vital Members of Accountable Care Organizations: Illustrating the Important Role that Pharmacists Can Play on the Health Care Team. Academy of Managed Care Pharmacy; March 2012. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9728. Accessed February 27, 2014.

[iv] Kwan JL, Lisha L, Sampson M. et al. *Ann Intern Med.* 2013;158(5_Part_2):397-403. doi:10.7326/0003-4819-158-5-201303051-00006.

[v] Improving Quality of Care for Medicare Patients: ACOs; Fact Sheet. CMS; November 2012. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Quality_Factsheet_ICN907407.pdf. Accessed February 27, 2014.

[vi] *Ibid.* at 6.

[vii] 42 USC §1320a-7a(b) "Gainsharing civil monetary penalty"; 42 USC 1320a-7b(b)(1) &(2) "Beneficiary inducement civil monetary penalty"; and 42 USC 1320a-7b(b)(1), (2), and (5) Anti-Kickback Statute.

[viii] 42 CFR Parts 409, 417, 422, et al. Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule. January 10, 2014.

[ix] Spiro S. The impact of EHRs on pharmacy practice. *Drug Topics*; April 2012. http://www.pharmacyhit.org/pdfs/Article.pdf. Accessed February 27, 2104.

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February 28, 2014

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Re: Request for Information (RFI) on Evolution of Accountable Care organization (ACO) Initiatives

Dear Ms. Tavenner and Dr. Conway:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on the RFI requesting comments on CMS/CMMI's Accountable Care Organization (ACO) initiatives for encouraging greater care integration and financial accountability. AdvaMed has been a strong supporter of ACOs since their inception in the Affordable Care Act. We recognize the importance of the goals of ACO initiatives as they seek to improve both the efficiency and quality of health care in this country and we believe that our members' technologies can play a critical role in assisting providers to achieve these goals. Our member companies are leading the way through advances in medical devices, diagnostics, and other advanced medical technologies. These products and services improve patient care quality and many improve efficiency by reducing the lengths of stay of patients in health care facilities, allowing procedures to be performed in less intensive and less costly settings, providing early detection of disease and infections, and improving the ability of providers to monitor care, among other benefits.

In this letter, we offer general comments that address beneficiary protections that we believe should be considered as CMS and CMMI explore new directions for ACOs to assume more financial risk for the cost of care. We have divided our comments into three major sections: First, our letter raises questions about the impact a transition to greater insurance risk for ACOs

could have on the broader health care marketplace and whether ACOs assuming full insurance risk and functioning more like Medicare Advantage plans raises competitive concerns. We also recommend that patient protections be incorporated into models that carry more financial risk for providers serving beneficiaries of the Medicare and Medicaid programs. The second section of this letter discusses specific recommendations that we offer to address concerns that the financial incentives underlying the ACO model can lead to stinting on care and compromised patient access to breakthrough treatments and technologies. We note that new ACO models including more financial risk for providers can increase the likelihood that beneficiaries may experience these problems. The final section of our letter recommends that CMS move beyond the 33 quality measures now used in ACO programs and incorporate additional measures from the robust range of measure areas available for application to the programs and asks that CMS consider two gap areas – among many that are possible – for future measure development and application to ACOs.

I. Transition to Greater Insurance Risk

The RFI is predicated on the notion that ACOs should take on more financial risk, expand their scope, involve multiple payers, and become a more common feature of the health care delivery system, even though there is relatively little evidence regarding the impact of currently configured ACOs on patients and other stakeholders. When the Medicare Shared Savings Program (MSSP) was implemented by CMS through final regulations, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) joined in a statement pertaining to antitrust enforcement policy regarding MSSP-participating ACOs. This statement identified an antitrust safety zone and offered ACOs a voluntary process for seeking expedited review of arrangements outside this safety zone. The statement also identified types of conduct that could raise competitive concerns. The two agencies also indicated their intent to closely monitor the competitive effects of ACOs.

We believe that CMS and CMMI should take a very guarded approach to expanding the reach of ACOs, especially since there is the potential for ACOs to have anti-competitive effects. We believe that more time is needed to assess the impact of current ACOs in various marketplaces and the nature of related anti-trust enforcement activities and findings. Such a measured approach will also provide an opportunity to assess the adequacy of the existing antitrust enforcement statement and related policies.

The RFI seeks input on the types of precautions that should be taken to protect beneficiaries if and when ACOs take on more insurance risk. First, AdvaMed believes that more balanced educational materials need to be prepared for beneficiaries potentially served by ACOs, including current ACOs. While beneficiaries, in theory, are not locked into an ACO and its providers, we believe that an ACO's referral patterns and other actions may effectively have the result of locking beneficiaries into ACO providers. Increasing financial risk is likely to bring greater pressures to control health expenditures by steering beneficiaries only to ACO providers or delaying referrals to specialists. Beneficiaries should be clearly informed that they may seek care outside an ACO. Effectively, the ACO is analogous to a point-of-service (POS) option in a

Medicare Advantage (MA) plan. Medicare Advantage enrollees with a POS option must be given notice that they can seek care outside of the Medicare Advantage provider network (see the requirements in 42 CFR §422.105(d)(2) regarding the evidence of coverage document).

In addition, beneficiaries should be informed about the full array of incentives that apply to ACOs, including those that could prove detrimental to beneficiary interests. CMS-prepared educational materials should not imply that ACOs can have only positive consequences for patients when so little is actually known about their impact on access to and the quality of care. In the Medicare Advantage program, for example, beneficiaries are entitled to information regarding physician compensation (see 42 CFR §422.111(c)(4).

Second, AdvaMed recommends that CMS and CMMI incorporate a broader range of patient protection provisions in ACO programs, especially if ACOs take on more financial risk, expand the scope of their responsibilities to additional items and services, and begin to resemble Medicare Advantage plans. At a minimum, these patient protections should include requirements that ACOs have grievance and appeals processes identical to the Medicare Advantage program. In addition, ACOs should provide options for their assigned beneficiaries to participate in clinical trials. We believe that granting beneficiaries such rights if and when ACOs transition to greater insurance risk would be preferable to only giving beneficiaries the choice of walking away from an ACO with which they have concerns about care or other grievances.

The beneficiary protections mandated for the MA program in Section 1852 of Medicare law were created to address concerns similar to the concerns that surround ACOs – ensuring beneficiary choice of providers and coverage, and ensuring that beneficiaries receive appropriate care in the face of pressures on providers and plans to reduce costs. One such basic protection is the requirement that MA organizations have a robust grievance process in place that provides beneficiaries an opportunity for resolving issues involving the provision of health care services where, for example, the beneficiary believes he or she has not received items or services to which he or she is entitled.

Having such recourse is far less burdensome and blunt than disenrolling from a plan and enrolling into another plan. CMS' regulations (see 42 CFR §422, Subpart M) require MA organizations to establish and maintain a formal grievance procedure, a procedure for making timely organization determinations, and appeal procedures that meet robust regulatory requirements regarding timeliness, responsiveness, and transparency by the MA organization. In certain cases, a member may be able to receive an expedited determination and reconsideration or response. Together, the grievance regulations amount to a meaningful review process for beneficiaries, with potential review by an independent review entity, an administrative law judge, the Medicare Appeals Council, or even judicial review. This creates opportunities for beneficiaries to challenge the plan in which they are enrolled on a variety of matters. AdvaMed believes these provisions should be incorporated into any future ACO models.

CMS also ensures that beneficiaries who are members of an MA plan and choose to enroll in a clinical trial are not required to pay additional cost sharing for the services in the trial, beyond the applicable cost-sharing in the MA plan for similar services provided in-network (see Medicare Managed Care Manual, Ch. 4, §10.7.1). MA plans are required to reimburse the difference between the cost-sharing paid by the beneficiary to receive services in the clinical trial and the cost-sharing that is otherwise applicable had the services been delivered as in-patient services within the plan. MA plans cannot limit the clinical trials in which a beneficiary can participate for this policy, and must reimburse the difference even if the member has not yet paid the clinical trial provider. This protection allows beneficiaries seeking innovative therapies to participate in clinical trials without facing financial barriers. We believe this protection is important for ACO beneficiaries, as well, and will become increasingly important as CMS contemplates expanding its ACO initiatives and requires ACOs to take on more financial risk. As we will discuss below, such changes may increase the potential for beneficiaries to have reduced access to innovative therapies.

As the number of ACOs approved for participation in the program has grown and beneficiaries assigned to them has expanded to the point that ACOs are now serving approximately 10 percent of total Medicare enrollees, the need for beneficiary protections similar to those in the MA program has become more apparent. We also believe these protections are necessary given the absence of detailed information about the steps CMS is taking to monitor care provided to beneficiaries in these programs. Including these beneficiary protections in the requirements for ACO participation in the program, as well as others discussed below for countering unintended consequences of the financial incentives of the program, would ensure that the proliferation of ACOs does not impinge patients' options and treatment.

II. Ensuring Patient Access to Appropriate Care

As noted above, AdvaMed has supported delivery reform models, such as ACOs, and their goals to achieve lower cost and higher quality health care. At the same time, we are concerned that the financial incentives in these and other delivery reform models, such as the Bundling Initiative, can have the inadvertent effect of discouraging providers from (1) considering the full array of treatment options, especially if they may increase costs above "benchmark" thresholds—we refer to this as stinting, or (2) using innovative treatments, technologies, and diagnostics that may bring value to the health care system over the longer term, but are more costly in the short run.

In addition, quality standards used for ACOs could discourage early adoption of new and better alternative treatments simply because the quality measures do not reflect breakthrough and innovative treatments. If a new approach to care is developed that may be superior to standard practice, and no special exception is provided for the new alternative treatment, physicians or hospitals may avoid adopting it because it will lower the ACO's quality score and, in turn, reduce shared savings.

These negative impacts can be avoided without undercutting the goals of the new payment and delivery systems by incorporating certain technical adjustments in the programs and by adopting other patient protection measures. We believe that these technical adjustments and patient protections become even more important for beneficiaries if CMS and CMMI proceed with implementing new ACO models that allow ACOs to assume more risk for the cost of care.

AdvaMed Recommendations for Addressing Patient Access to Innovative Care Through Payment and Quality Score Adjustments

Our recommendations would provide adjustments for a limited number of innovative treatments or diagnostics that are first reviewed and approved by CMS after meeting certain criteria. These adjustments would be used for a limited period of time to allow time for these treatments and diagnostics to be reflected in new benchmarks or incorporated in quality measurement to the extent they become the standard of care. For purposes of payment for innovative treatments, the cost of approved innovative treatments would be removed from the calculation of benchmarks and Medicare expenditures when calculating savings or losses. Where the barrier to adoption is a quality standard, quality measurement would exclude the case with the new treatment from the provider or physician quality score. With these adjustments, the disincentives to use an innovative treatment or diagnostic would be neutralized and ACO providers would make decisions purely on medical grounds.

CMS Review of New Treatments and Process: CMS would establish a process for manufacturers or developers, to identify breakthrough technologies/treatments meeting the criteria below. This process would be similar to the one now used by CMS for New Technology Add-On Payments. Manufacturers and developers would provide CMS the estimated incremental increase in expenditures that would result from each use of the treatment in a given year. They would also provide CMS the data and methodology for such estimates as part of the application process to assist CMS in determining whether a treatment or technology warrants special accommodation and what adjustments would be made. If approved by CMS, the adjustments would apply to use of the technology across all ACOs.

CMS would also allow individual ACOs/bundled payment awardees to request an adjustment if they were to adopt breakthrough/ high cost treatments in advance of other providers. The adjustment could be applied to the individual awardee or all awardees using the treatment.

Recommended Eligibility Criteria for Payment Adjustments: CMS would establish the following criteria to authorize adjustments to benchmarks and calculations of Medicare expenditures:

- New technologies/treatments/diagnostics that offer substantial clinical improvements and represent a higher cost to the awardee than use of current therapies;

- Existing treatments or diagnostics that offer significant therapeutic advances for new populations or conditions and that represent a higher cost to the awardee(s) than existing treatments for those populations.

Recommended Eligibility Criteria for Quality Measurement Adjustments: CMS would establish the following criteria to authorize adjustments to calculations of Medicare's individual quality scores:

- The new treatment, service, or diagnostic test is potentially a superior clinical substitute for the current treatment, service, or diagnostic test used for quality measurement.
- The treatment, service or diagnostic test is clinically equivalent to existing treatment, service, or diagnostic test but provides advantages for patients or providers, such as ease of administration or reduced discomfort.

Length of Adjustment Period: At the time of qualification, CMS would determine the length of a payment and/or quality adjustment period based on a reasonable assumption of the time needed for the product to be reflected in benchmarks. Generally, this would be a period of three to five years from the time of designation. In the case of an alternative quality measure, the adjustment period would end if a consensus quality standard body determined that a new quality measure should be developed or the new treatment or diagnosis should replace the existing one.

Making Public Provider Financial Rewards Received under ACO Programs

Incentives for reducing costs have the potential to lead to stinting on care, denying specialty referrals or higher cost tests and interventions, or selecting cheaper technologies, even when the specialty referrals or higher cost tests and interventions are the most appropriate treatment for the individual. Furthermore, the limited payment window used to evaluate costs and calculate shared savings in ACO programs provides significant disincentives to treat patients with interventions that demonstrate long-term value. This may lead to focus on short-term cost savings even when this is not in the best long-term interest of the patient.

One way to monitor for a connection between suspiciously high financial gains by individual physicians and the withholding of the most appropriate treatments and technologies due to cost would be to publicize the amount of shared savings or gainsharing rewards that physicians receive as a result of their participation in an ACO. This information could then be coupled with data on the treatments and technologies that the beneficiary who is assigned to the ACO receives. AdvaMed strongly urges CMS to create and implement policies that would allow for such disclosure and transparency that will protect Medicare beneficiaries and uphold quality in the Medicare program. To this end, AdvaMed recommends that CMS and individual ACOs make available to the public both aggregated data and individual physician shared savings and gainsharing rewards received by practitioners participating in these programs.

Rigorous Monitoring of Care Received by Beneficiaries Assigned to ACOs

CMS recognizes that quality measurements currently applied under ACO programs are not adequate to avoid many forms of stinting on care. While the agency announced in the final MSSP rule that it would be conducting monitoring and oversight activities to guard against stinting, it is not clear at present what specific form these activities have taken. AdvaMed recommends that monitoring activities not be limited to claims data analysis, but also include medical record audits of beneficiaries in ACOs. Evaluations should also compare the care and health outcomes of beneficiaries assigned to ACOs with professionally recognized standards, as well as to non-ACO beneficiaries' utilization of specific services, including a review of referrals to medical specialists.

III. Future Quality Measures

The RFI asks for comments on additional quality measures that should be considered for ACO programs if an ACO becomes responsible for all covered lives in a geographic area. AdvaMed supports the alignment, harmonization and implementation of quality measures in ACO programs. However, the current list of the 33 required quality measures that are part of the ACO quality performance standard do not reflect the robust range of measure areas potentially available for development across all CMS reporting and performance programs, including ACOs. We look forward to CMS adopting in the near future an expanded list of quality measures that would apply to ACO programs. In the short term, AdvaMed recommends that CMS consider the following two gap areas—among many that are possible-- for future measure development and application to ACO programs: (1) Malnutrition; and (2) Wounds.

Although evidence shows that the decline in nutritional status and wounds across all care settings impacts patient outcomes, resource use and costs, there are currently no quality measures to address gaps in management of malnutrition and wounds through screening, assessment, nutritional intervention, execution of nutritional /wound care (treatment) plan, and care coordination in any CMS program. While CMS has acknowledged the impact of undernutrition (and obesity) on patient outcomes with the implementation of a body mass index (BMI) quality measure in the Medicare Shared Savings Program, patients may be malnourished regardless of BMI as they may be deficient in the macro- and micro-nutrients needed to help promote healing and reduce medical complications. Malnutrition and wound care quality are benchmarks of an effective integrated care delivery system.

Summary

In summary, AdvaMed recommends that CMS and CMMI incorporate several patient protection policies into the existing structure of ACO programs implemented to date. These would include payment and quality score adjustments to neutralize disincentives that might discourage

providers from using innovative treatments and diagnostics that are appropriate for the condition of a particular patient but are more expensive than existing alternative treatments and/or not yet reflected in quality measures used in the programs. We also recommend that ACOs provide beneficiaries more complete information about the implications of the financial incentives that undergird the ACO program and that CMS and ACOs make available to the public both aggregated data and individual physician shared savings and gainsharing rewards received by practitioners participating in these programs. These patient protections, together with rigorous monitoring of care received by beneficiaries assigned to ACOs, will help ensure that beneficiaries receive high quality of care, especially if CMS and CMMI proceed with allowing ACOs to assume more risk for the cost of care. In this regard, we believe that more time is needed to assess both the impact of current ACOs in various marketplaces and the adequacy of the existing antitrust enforcement statement and related policies. At a minimum, ACOs assuming greater financial risk for the cost of care should be required to follow Medicare coverage policies, have grievance and appeals processes identical to the Medicare Advantage program, and be required to allow patient participation in clinical trials. Finally, AdvaMed recommends that CMS move beyond the 33 quality measures now used in ACO programs and incorporate additional measures from the robust range of measure areas available for application to the programs and asks that CMS consider two gap areas – among many that are possible – for future measure development and application to ACOs.

Thank you for your consideration of our comments. If you have any questions, you may contact me at dmay@advamed.org or 202-434-7203 or Richard Price at rprice@advamed.org or 202-434-7227.

Sincerely,

Donald May
Executive Vice President
Payment & Health Care Delivery Policy
AdvaMed

March 1, 2014

Submitted Electronically via http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for Information Concerning Pioneer ACOs and Evolution of the ACO Model

Dear Administrator Tavenner:

Aetna welcomes the opportunity to respond to the Request for Information ("RFI") issued by the Centers for Medicare and Medicaid Services ("CMS") and the CMS Innovation Center, concerning Accountable Care Organizations ("ACOs"). We appreciate the leadership of this Administration in launching multiple payment and delivery system reform initiatives, including the important ACO provisions authorized by the Patient Protection and Affordable Care Act (the "ACA").

Value-based, patient-centered care models, including accountable care organizations (ACOs), are an important component of Aetna's vision for a more connected and effective health care system. Our Accountable Care Solutions (ACS) business exemplifies how we are advancing new models of payment reform in doing business with providers. In our 32 ACS agreements, rather than paying for itemized services, we are developing innovative models to share risk and reward with providers. We believe that working together with providers, we can enhance quality and lower costs. Providing value -- by improving patient health -- is the goal, not more treatment. We have to reduce the underlying cost of providing health care.

We are hopeful that the evolution of Pioneer ACOs and ACOs that participate in the Medicare Shared Savings Program, established by section 3022 of the ACA, will encourage the development and spread of effective ACOs as a delivery mechanism throughout the various insurance markets. But as much as we are encouraged by the Administration's interests in increasing value-based contracting and expanding opportunities for ACOs, we also recognize the challenges that remain and the policy changes needed to ensure ongoing, measureable success.

Our letter responds to the specific questions posed by the RFI, but we also want to take the opportunity to suggest specific actions that could further replicate and extend the encouraging early results of ACOs.

1. **Establish benchmarks for moving to value-based payment models.** Many providers have no plans to participate in value-based contracting and are taking a wait-and-see approach. Public policy and business actions which demonstrate private sector and Federal government intent to further value based contracting will serve to ignite movement toward value-based care. For instance, Aetna has stated that nearly half of our contracts will be value-based ones by 2017.

2. **Improve the incentives.** Current programs require adjustments to be more successful. For example, we believe CMS should realign risks and modify quality standards in the Pioneer ACO program. Surveys of ACOs have indicated that investments are larger than originally anticipated. However, new programs, technologies and resources are required to make the transition a successful one, as evidenced by the early ACOs. The financial rewards are not sufficient for most providers to offset the investment and associated risk. Alterations in the savings share of the program over a defined time period would encourage greater participation. Aligning other Federal programs such as Meaningful Use could further improve the rewards for ACO success.

3. **Paint a clearer picture of the future state.** Many delivery systems are hesitant to commit to programs which require ongoing cost reductions in order to create a sustainable financial future. Pioneer and MSSP programs should define a new business model where health care costs, health care business profitability, private sector leadership, and community health and wellness are tied together. Pioneer or MSSP programs could offer transitions to Medicare Advantage or other new programs.

4. **Provide better data and analytic support**. Due to delays in data availability and accuracy, many of the ACOs were "flying blindly" for parts of their year. Ready access to data about patients – who they are, where they are receiving care, what conditions they have – is essential if the ACOs are to coordinate and improve their health outcomes.

As the ACO programs evolve, we remain committed to working with CMS to develop credible targets, to use appropriate levers to achieve them, and can be effectively communicated to patients, providers, and payers alike. To that end, we are pleased to submit the attached technical appendix with comments regarding a number of the questions that CMS asked in its RFI.

Aetna is pleased to have the opportunity to respond to the ACO RFI. We would be pleased to discuss our responses with you in more detail. Should you have any questions, please feel free to contact me.

Sincerely,

Steven B. Kelmar
Executive Vice President, Corporate Affairs

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ADDENDUM to AETNA COMMENT LETTER
Detailed Technical Responses
Request for Information Concerning Pioneer ACOs and Evolution of the ACO Model
March 1, 2014

I. To Increase Participation in the Pioneer ACO Model, CMS Should Realign Risks and Modify Quality Standards

The RFI asks for recommendations as to how CMS may increase participation in the Pioneer ACO Program. We believe that there are several key reasons why provider interest in the first round of the Pioneer ACO Program did not match the level of interest in the Medicare Shared Savings Program. These reasons primarily relate to the burden of complying with the Pioneer Model's quality measurement standards.

A. *Modify Quality Standards*

A number of participants in the Pioneer ACO Program, as well as providers who considered the program, have expressed concern that the Pioneer Model's quality measures are set too high to achieve – especially for those ACOs that already had high quality levels.

As currently structured, Pioneer ACOs must report on four domains with 33 quality measures, weighted equally. The requirement to report on so many quality measures may be too costly and burdensome for many ACOs, especially during their first several years of participation in the Pioneer program. We therefore suggest a phase-in of quality measure requirements for new participants in the Pioneer Model, similar to the Physician Group Practice demonstration project in which CMS phased-in the requirement to report as to 32 quality measures.[1]

We also note that many ACOs – both Pioneer ACOs and Medicare Shared Savings Program ACOs – have expressed concern that the data from CMS was very challenging to work with, and could not be utilized by a receiving ACO in a timely or actionable manner to drive the behavioral changes needed amongst both participating clinicians and patients. A guarantee of more timely and more complete data from CMS could encourage greater participation in the Pioneer Program (and the Medicare Shared Savings Program).

Recommendation: A reassessment of the quality targets could make the Pioneer Program more attractive by either lowering the targets or allowing more time for an ACO achieve the targets (or both). To that end, we recommend aligning the required quality measures reported for the Pioneer ACO Program with those required under the Medicare Advantage program. In addition, we believe that providing data to ACOs in a timelier manner, in a format that can be readily utilized, would encourage greater participation.

We also suggest modification of the benchmark to permit providers that are already efficient the opportunity to fully participate in shared savings. The benchmark could compare an ACO's performance against those of similarly-situated regional practice

[1] *See* 76 Fed. Reg. at 19536.

groups, similar to the Physician Group Practice Demonstration ("PGP") approach, under which participating PGP providers are benchmarked against the experience of local Medicare beneficiaries not assigned to the participating PGP.

B. *Pioneer ACOs Should Not Be Required to Have Reserves*

The RFI asks whether CMS should eliminate the requirement that a Pioneer ACO attain a specified level of savings before it qualifies for the Population-Based Payment ("PBP") methodology, and whether Pioneer ACOs should instead be required to have a specified level of reserves. We believe that many, if not most, ACOs would be reluctant to enter into arrangements whereby they would have to maintain a specified levels of reserves as a condition for Pioneer ACO participation. Requiring ACOs to have reserves could potentially subject ACOs to state insurance law, which would add even more compliance burdens. Moreover, maintaining a specified level of reserves would not be feasible for many ACOs, given the very significant start-up and infrastructure costs that ACOs, by definition, must incur, and the already thin margins on which many ACOs currently operate.

Recommendation: Pioneer ACOs should not be required to maintain reserves. If CMS nonetheless determines that a reserve requirement is desirable, CMS should expressly allow providers and issuers to jointly form a Pioneer ACO, so that providers and insurers can jointly own the ACO and share in the reserve requirements.

II. Evolving the ACO Model

The RFI also requests recommendations as to how the ACO model may be "evolved" beyond its current standards, and we appreciate CMS's specific request for input regarding the ACO models of private payers. Aetna has participated in dozens of ACO projects in both the Medicare and commercial insurance markets, and our Medicare Advantage ("MA") program has established collaboration pilots with 47 primary care practices. As such, we believe that we have unique insight as to the following issues on which CMS has solicited comment:

A. *Transitioning ACOs to Capitated Models*

Aetna believes that CMS should offer ACOs capitated payments similar to the MA program – with participating ACOs accepting full insurance risk – but only under carefully delineated circumstances. As noted above, we believe that it is critical that CMS encourage ACO participation by a wide variety of provider organizations, and not just those comprising large hospital systems and large provider groups. Any ACO arrangement requires significant start-up investments and considerable on-going expenses, and these expenses already discourage smaller providers from participating in ACOs. If CMS were to require that ACOs accept capitation, it would further discourage participation in ACOs by providers who are not equipped to accept full insurance risk, especially smaller providers from whom most patients receive their care.

Likewise, even ACOs with demonstrated experience in sharing in downside risk – whether through participation in the Pioneer Model or Medicare Shared Savings Program – may find it difficult to transition to a full-risk model, at least without the participation of non-ACO providers, such as insurers, who can offer financial and strategic resources that will more readily enable the ACO to satisfy the requirements of a capitated ACO arrangement with CMS. These resources include the infrastructure to execute a complex set of activities that are traditionally beyond a provider organization's capabilities, such as effective care management, advanced IT implementation, and the

ability to negotiate and administer provider contracts to assure an adequate and robust network.

Recommendation: CMS should not *require* any and all ACOs to accept full insurance risk. Rather, a capitated model similar to the MA program would be appropriate for ACOs only under the following conditions:

- The ACO must have participated in the Pioneer ACO Program, or Track Two of the Medicare Shared Savings Program, thereby demonstrating its ability to take on partial risk;
- During its time in either the Pioneer or Medicare Shared Savings Program, the ACO must have hit its medical cost targets;
- The risk corridor for the ACO should slowly increase over a reasonable number of years, so that the jump from partial to full risk is not drastic;
- Quality measures applicable to the ACO increase over a number of years, as the ACO demonstrates a greater tolerance for risk**;** and
- Medicaid experience is carved out of capitation payments

B. *Full-Risk ACO Models Will Require Reduced Cost-Sharing for ACO Participants*

We also note that if CMS moves to full-risk ACO arrangements, certain benefit enhancements – such as the availability of reduced out-of-pocket costs to participants – will be required to improve the odds for a successful transition. Experience with the Pioneer ACO Program has demonstrated that Medicare Part A and B participants who lack "Medicare Supplement" or "Medigap" insurance still face considerable cost-sharing expenses that discourage them from seeking even fully-covered wellness exams, out of fear that the wellness exam will prompt other tests or laboratory services that the patient cannot afford.

Recommendation: If CMS moves toward full-risk ACOs, there should be greater incentives for ACO participants to affirmatively seek out primary care and treatment, either in the form of:

- Reduced copayments (or other cost-sharing), or
- The availability of inexpensive supplemental or "gap" insurance that will cover ACO participants' out-of-pocket costs.

C. *Full-Risk ACOs Will Need to Enter Into Arrangements With a Number of Non-ACO Providers*

The RFI recognizes that if CMS moves toward a full-risk ACO model, ACO providers will need to enter into arrangements with a number of non-ACO providers.[2] A successful

[2] We use the term "ACO provider" as it is defined for purposes of the Medicare Shared Savings Program. Under the MSSP, the following participants (or combinations thereof) are eligible to form an ACO:

- A physician, physician assistant, nurse practitioner or clinical nurse specialist in a group practice arrangement ("ACO Professionals");
- Networks of individual practices of ACO professionals;

ACO will need to offer integrated clinical communication and coordination with, among others, home health agencies, long term acute care centers ("LTACs"), skilled nursing facilities ("SNFs"), and other post-acute care facilities. The integration of so many different services and providers within an ACO will require sophisticated health information exchange ("HIE") and electronic health records ("EHR") technologies.

As discussed above, small provider groups often lack the capital and infrastructure necessary to form an ACO and to administer the programmatic requirements of a CMS-governed ACO program. And, smaller provider groups will very often lack access to the financing that will be necessary to make the upfront investments required by a full-risk ACO model. Indeed, commercial lenders are unlikely to respond quickly or favorably to requests by ACOs for loans or lines of credit, given the complexity of healthcare payment and the significant change to payment that the ACO reimbursement method represents. Non-ACO participants, however, can provide both financial and strategic resources that will enable provider groups to satisfy ACO requirements.

Among other things, non-ACO participants can be of particular help to smaller physician groups and hospital systems that do not have the significant upfront capital necessary to develop care management systems and to invest in health information technology. For example, insurers can assist the ACOs with which they partner in carrying financial risk that may be required as a condition for participation in a CMS-governed full-risk ACO arrangement (*e.g.,* reserves). And software vendors and insurers can offer critical strategic support and services that will enable an ACO to satisfy the myriad of requirements set forth in CMS rules, and thereby assist in achieving the ACO's goals of improved quality and greater cost efficiencies. For example, vendors and insurers have leveraged administrative data to track the health of large populations and ensure preventive care or disease management interventions are completed and up to date. These insights can be shared with full-risk ACOs and used to monitor the health of the ACO's patients. New tools and improved data integration between administrative data and clinical data are important gaps that need be filled to drive value for ACOs. Non-ACO participants such as insurers could also provide care management support staff (telephonic or embedded care coordinators) to help smaller groups or those with limited resources to scale their staff.

Unless smaller practices receive meaningful financial and support services from non-ACO providers, the start-up costs of a full-risk ACO could create barriers to market entry that only large physician group practices and large hospital systems could overcome. This, in turn, could reduce competition and innovation, needlessly limiting the positive impact that ACOs can have, particularly in controlling costs.

Recommendation: CMS should allow non-provider organizations, such as vendors and insurers, to meaningfully participate in the governance and operation of a full-risk ACO, as a means of encouraging these organizations to offer financial and strategic resources that will enable the ACO to satisfy CMS's requirements for full-risk ACOs.

- Partnerships or joint venture arrangements between hospitals and ACO professionals;
- Hospitals employing ACO professionals;
- Critical access hospitals that bill under Method II;
- Rural health centers; and
- Federally qualified health centers.

Additionally, similar to the “Meaningful Use” program that CMS adopted for providers who use certified EHR technology, CMS could provide financial incentives to ACO participants for clinical data connectivity with post-acute facilities.

D. *Part D Expenditures*

Currently, providers do not have sufficient data regarding Medicare Part D expenditures to enable an ACO to accept risk for such expenditures. For an ACO to accept Part D risk, there would need to be coordination of a provider’s clinical data with laboratories, but the cost of such coordination is substantial and beyond the capabilities of many providers looking to join an ACO (especially under a full-risk model).

Recommendation: To help reduce these barriers to the integration of Part D expenditures into care delivery, CMS could establish a program, similar to the Meaningful Use program that encourages providers to adopt certified EHR technologies, which provides financial incentives to providers for integrating their clinical data with labs.

February 28, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Re: **Request for Information: Evolution of ACO Initiatives at CMS**
Submitted electronically at: http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/

Dear Administrator Tavenner:

The Alliance of Community Health Plans (ACHP) is pleased to respond to CMS' Request for Information (RFI) on the Evolution of ACO Initiatives.

ACHP is a national leadership organization that brings together innovative health plans and provider groups that are among America's best at delivering affordable, high-quality coverage and care in their communities. Member plans provide coverage for more than 16 million people in the commercial market, Federally-facilitated and state Marketplaces, Medicare, Medicaid, and federal, state, and local public employees. Members also provide administrative services for self-insured employers. The community-based and regional health plans and provider organizations that belong to ACHP improve the health of the communities they serve and are on the leading edge of patient care coordination, patient-centered medical homes, accountable health care delivery, information technology use, and other innovations to improve affordability and the quality of care that patients receive.

ACHP supports efforts by CMS to enhance accountability for care, health outcomes and the cost of care for Medicare and Medicaid beneficiaries. As CMS considers the evolution of the ACO initiative, we urge you to take the opportunity to consider how ACOs can drive accountability both in Medicare and across the entire health care system. We believe future ACO initiatives should incorporate the following principles:

1. ACOs should be responsible for the total cost of care for services they provide. In addition to setting targets, we believe this requires that ACOs accept two-sided risk for losses and savings, not just shared savings. However, we do not believe that the ACO model should necessarily shift to assumption of full risk. Instead, the model should be developed as a vehicle for provider accountability through shared risk, and CMS can test a range of models, including its current Pioneer approaches, with partial capitation and partial fee-for-service (FFS) payments. It could also consider a variant of a medical home model for ACOs, combining some portion of FFS payments with a monthly prepaid management fee, along with shared risk for performance. We suggest that CMS consider that when an

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ACO decides it can better serve its community as a fully-insured, full-risk model, it should be transitioned into the Medicare Advantage program.

2. ACOs should be used to further the integration of financing and the delivery of care. We believe the most effective arrangements to provide high value care are those in which the incentives of payers and providers are aligned. This requires developing an infrastructure for implementation of best practices, care management protocols, and coordination across providers and settings of care, backed by payment models incorporating agreed-upon goals for quality, patient experience, and cost.

3. ACOs will not be able to effectively coordinate care and manage costs without the inclusion of pharmacy. We recommend that the ACO model include Part D, with the opportunity to test different arrangements between the ACOs and Part D sponsors. Enrollees in the FFS program should be able to obtain Part D coverage at the same time they take advantage of ACO models in their community.

4. Over time, the involvement of additional payers in ACOs, with aligned measurement, payment incentives, and accountability for achieving quality and cost goals – and appropriate oversight to assure a level playing field – could further promote system-wide reforms in the delivery of care, to the benefit of Medicare, the community, and the health system at large.

5. Beneficiaries and providers require access to a consistent set of metrics across programs in order to promote informed choices. CMS should advance steps to align cost, quality and patient experience metrics among ACOs, MA and Part D plans, and the FFS program. If an incentive program were put in place to recognize high performance across these three areas of metrics, it would be a powerful mechanism to drive accountability across the system.

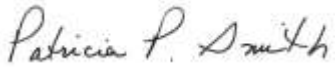
We recognize that these principles reflect long-term goals. In the shorter term, while we support CMS' policy goal to enhance accountability through ACOs and other means, we are concerned that the RFI may assume a more significant capacity for execution than may be available to shift to the next stage of ACO development. With the recent addition of 123 Medicare Shared Savings Program (MSSP) ACOs, there are now 343 such ACOs, but only five that are at two-sided risk. The Pioneer demonstration involves only 23 participants. While in total that may be a reasonable basis for testing ACO approaches, serving about 5 million beneficiaries, experience to date remains limited. The providers involved, CMS, and beneficiaries are in the early stages of learning how to understand utilization data and existing care delivery patterns, targets and benchmarks, and, most importantly, developing the profiling and care management protocols and incentive structures to actually improve care and costs.

ACHP members are acutely aware of the time and investment required to develop the infrastructure that accountability requires. We recommend that, even as CMS develops ideas for the next set of policy options, it focus in the near term on provider and beneficiary understanding and capacity building in the initial ACOs so that the agency and the providers involved can identify and replicate the elements of successful models. That work, in turn,

will help to establish credibility with other providers and beneficiaries in spreading new ACO models to communities across the country.

ACHP appreciates this opportunity to comment on the Request for Information and would be happy to respond to questions or provide additional information on these issues. If you have any questions, please contact Howard Shapiro, ACHP Director of Public Policy, at hshapiro@achp.org or 202-785-2247.

Sincerely,



Patricia P. Smith
President and CEO

Joanne Lynn, MD
Director, Center for Elder Care and Advanced Illness
Altarum Institute
joanne.lynn@altarum.org
202-776-5109

March 1, 2010

RE: CMS – Request for Information
Evolution of ACO Initiatives at CMS

The Center for Elder Care and Advanced Illness at the Altarum Institute (Joanne Lynn, MD, Director), is focused upon how to construct better models of care that will allow the U.S. to ensure that people living with the functional disabilities and chronic conditions typically associated with advanced age are able to live well at a cost that their families and the nation can sustain, The number of frail elderly persons is projected to increase slowly for the next fifteen years, and then to increase rapidly as much of the Boomer generation transitions into advanced old age. Without substantial delivery system reforms, the country cannot sustain the costs and will be forced to impose inadequate services on tens of millions of its citizens. We are among those leading reform efforts aimed at ensuring that the country is preparing to provide reliable and desirable services at a lower per capita cost.

We see the ACO idea as a very important vehicle for substantial innovation and reform. However, following on the agency's second area of focus, "suggestions for new ACO models that encourage greater care integration and financial accountability," We encourage CMS to make substantial changes to the current implementation, at least on a demonstration and innovation basis. The comments below respond to the particular queries in the RFI, but the overall framing is that, for this part of life, when we are living with substantial and progressive disabilities, reforms must look to require far greater coordination, monitoring, and management of a care system that is organized, at least in part, at the local level. Thus, we advocate that CMS allow development of "Accountable Care Communities" (or "MediCaring ACOs") for all frail elders residing in defined geographic areas, initially as a test of the concept, and that in so doing, the agency take steps to build a more solid infrastructure of appropriate person-centered care metrics and service and financial relationships with providers of social supports that will be necessary to achieve success and decrease per-capita costs..

To adequately serve a population of frail elders, whose needs span the breadth of hospital services through long-term services and supports to adequate housing, a range of reforms are necessary. A blueprint for the process of establishing ACOs that serve a targeted population of frail elders and that are anchored in a community over the long run could be outlined as follows:

1) Identify and enroll on a voluntary basis a cohort of frail elderly Medicare beneficiaries (for example, those with 2 ADLs or more, or those needing constant supervision, or a diagnosis likely to lead to these conditions in one to two years);

2) Conduct a much more comprehensive assessment than is normally done; construct a longitudinal care plan that all service providers adhere to and which reflects the beneficiary's treatment preferences and forward-looking goals; and design novel person-centered and experience of care measures that monitor the effectiveness of this plan in achieving the elderly person's goals ;

3) Record, expand and deliver services in optimized care plans, encompassing not just adapted medical services, but also relevant supportive services in the community;

4) Modify as appropriate the mix of services available to enrolled beneficiaries, aiming for fewer hospital admissions and fewer long-stay nursing home placements, along with more services delivered at home;

5) Develop a local organization capable of monitoring the local system and moving supply and quality toward optimal, which could be a coalition of providers and local planners, a semi-governmental entity, or a community-based provider entity that contracts with other providers and maintains the trust of the public; and

6) Once sufficient cost data on services delivered become available, construct a shared savings ACO-like financial model to sustain the Accountable Care Community model.

General Comments:

In general, community-anchored ACOs hold the promise of delivering the care that is needed for frail elders through greater integration, more comprehensive care planning, and active monitoring and management of the delivery system. A number of overarching areas that need to be addressed in helping the ACOs move forward:

- ACOs organized as Accountable Care Communities for frail elders need permission to manage and combine separate funding streams. Separate funding streams can create or reinforce care silos if flexibility in payment methodologies isn't allowed. New generations of ACOs must integrate medical care with social support services behavioral health and other community-funded services, and this requires savings from medical funds to support housing, transportation, and caregiver support – and consideration of OAA and local supportive care funding in the care planning and system management.
- Data sharing across providers is key to integration and coordination of services. Medical and community providers have distinct data infrastructures in place (e.g. different or no electronic health records), which reinforces existing care silos. CMS should encourage sharing of information and data across systems to support coordinated care interventions. Trying to allow sharing of care plan information with entities that are not covered under HIPAA brings about challenging problems that could be mitigated with guidance from

CMS or HHS. Aggregating care plans and quality measures in a geographic area would enable community-based management of the care delivery system, but this also is made challenging without permissive interpretations and guidance from CMS and related agencies.

- ACOs should be leaders in developing true professional integration of the care continuum inclusive of the broad range of healthcare providers -- nurses, physicians, dieticians, social workers, pharmacologists and others who serve vulnerable elders.
- Quality measures must be developed that reflect the needs of the frail elder population. Metrics are especially needed to measure performance across the continuum of care, not just within delivery silos but across different providers as frail elders move around. Also, ACOs and others need metrics that report outcomes in relation to the particular patient's priorities – not just the professional standards we do now, or the aggregated patient perspective, but the specific patient's perspective.
    - Local entities that bring together the payers and the providers to form a publicly trusted ACO to serve the frail elders (and perhaps some other vulnerable populations) offer many attractive advantages asthe next generation of ACOs.
- Finally, while adding more risk to ACOs has the potential to drive incentives for quality and cost effectiveness, CMS must first review the initial set of ACO data to inform the direction for the next generation of ACOs. Adding risks makes it more and more a process available only to large players with sizable reserves and could make it impossible to develop an ACC (an ACO serving a community's frail elders) in a moderate size community with limited resources

We have developed some specific responses to certain of the RFI sections as follows:

Section I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters.

The Pioneer model is not particularly adapted to an ACO focused on frail elders in a community. However, CMS offers, in the section on the Pioneer ACO focus, the observation that Pioneer ACOs can "transition to population-based payments (PBP) that offer revenue flexibility to provide furnish (sic) services not currently paid for under Medicare Fee-for-service (FFS), and to invest in care coordination infrastructure." PBP could be a good idea for frail elders from early on – and could be necessary in order to achieve savings, sustainability, and scaling up to large numbers of communities.

Section II: Evolution of the ACO Model

A. Transition to greater insurance risk

While generally it may be premature to consider increasing the risks for ACOs until they are more mature and more performance data is available, higher risks are especially troublesome to consider for a new model Accountable Care Community, aiming to use shared savings to support community-based monitoring and management and to subsidize

in-community supportive services. Increasing risk would make it more difficult for local governments and coalitions to try out this model.

3) Are there services that should be carved out of ACO capitation? Why?

There is an urgent need for re-insurance for relatively small entities like many ACCs would be. Otherwise, just the happenstance of a bad flu year or some early clients needing extensive medical services would bankrupt the operation before it really got underway.

The ACO rule lists eligible providers and suppliers. Rather than carve-out providers and services CMS should consider expanding the list to include other types of Medicare-enrolled providers and suppliers beyond those listed in statute. ACOs hold the promise to coordinate care along the full continuum of care beyond just physicians and hospitals. For the true coordination of care for Medicare beneficiaries, after-hospital providers and long-term services and supports should be included in the ACO structure. For frail elders, mental health needs are so intrinsic to overall good care that they certainly should not be carved out.

5) What Key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in MA would not be appropriate for ACOs assuming full risk?

At this time the type of standards applied to Medicare Advantage Plans contracting with Medicare should also apply to contracting ACOs if they move to assuming full risk. These include requirements related to solvency, utilization review, quality assurance, and consumer information and protection. As ACOs become more mature it is possible that less stringent solvency standards could apply to ACOs than those applied to Medicare Advantage once the ACO structure demonstrates adequate incentives for customer service, quality standards, and efficiency..

The ACO probably has to be able to enroll in order to activate and monitor at least the appeals and consumer protections – so, many of the MA provisions will require the major change in ACO plans of having the ability to enroll or at least to declare oneself (as a beneficiary) to be aligned with the ACO. Also, MA plans cannot provide many additional services because they count as inducements – including integrating most supportive services. Since that is a legitimate inducement to join a local frail elder ACO, that restriction would need to be voided. MA plans generally can enroll only once each year –a frail elder ACO or ACC need to be able to enroll quickly.

B. Integrating accountability for Medicare Part D Expenditures

The current incentives in Part D are often contrary to the best interests of frail elderly patients, since they aim mainly to reduce utilization, especially of high-cost medications. A frail elder ACC must put medications into the plan of care along with everything else, and to be accountable for the total costs. Medication costs may well increase with optimal

care plans, which is welcome when it both increases patient well-being and diminishes utilization of costly treatments.

C. Integrating accountability for Medicaid Care Outcomes

An ACC (ACO for frail elders) needs to be accountable for long-term care outcomes, certainly. Indeed, one of those would be the likelihood of spending down to Medicaid, given the frail elder care system in the community. In addition, the system should measure whether the care plans achieve outcomes consistent with individual patient priorities and whether the overall costs (to public funds and to private resources) are reduced.

D. Other Approaches for Increasing Accountability

On page 7, section D, item#1 , the RFI mentions "A provider-led community ACO would be held accountable for total Medicare, Medicaid, and CHIP expenditures and quality outcomes for all… beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns." This is the right idea, moving forward. We approve, though we would encourage initial work on frail elders where so much expenditure lies, the system now is so dysfunctional, and politics and practice align to make rapid change possible. A successful frail elder ACC could grow to take on younger populations, or disabled populations. We certainly see the merits of allowing a focus on geographically aligned populations.

E. Multi-Payer ACOs

With regard to multi-payer ACOs, Section E, an initiative targeting frail elders needs to work nearly entirely with financial entities that originate with Medicare and Medicaid (insurance companies, managed care) – and perhaps also with VA, HIS, and DOD, especially in some communities. There may need to be outreach to MediGap and the few LTC insurance companies. Older Americans Act financing and local funds will need consideration. However, mostly, our frail elder population needs coordination of financing from Medicare, Medicaid, and private assets. Requiring conventional insurance participation would not be very important.

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February 28, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop 314G
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Centers for Medicare and Medicaid Services (CMS) Center for Medicare and Medicaid Innovation; Request for Information (RFI): Evolution of ACO Initiatives at CMS

Dear Administrator Tavenner:
On behalf of the nearly 13,000 U.S.-based members of the American Academy of Dermatology Association (AADA), I am responding to the Centers for Medicare and Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) Request for Information on the Evolution of Accountable Care Organization (ACO) Initiatives. The AADA is committed to excellence in medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology and dermatopathology; and supporting and enhancing patient care to reduce the burden of disease. The AADA appreciates the opportunity to provide comments to CMS and hopes CMS will take the AADA's concerns and recommendations into consideration when formulating future policy.

Introductory Remarks
The AADA commends CMMI on its interest in developing new iterations of Pioneer ACOs that encourage greater care integration. We believe the Pioneer program has made efforts to stay nimble and flexible in addressing the evolving health care environment and the needs of both patients and providers. The AADA supports the concept of accountable care, but believes value-based care is not a "one size fits all" proposition. Accordingly, we believe it is important to continue working to develop new payment and delivery models that are viable for physicians in all specialties and practice settings.

Specialty Physicians and the Transition to Value-Based Care
We would like to express our concerns regarding the role of specialists, including dermatologists, within the next generation of Pioneer ACOs. Payment and delivery reform seen in ACOs now emphasizes primary care because many health care experts believe primary care physicians (PCPs) can help to improve the quality of care by strengthening preventive care and coordinating patient care. In contrast, specialists are seen by some ACOs as cost centers, not as partners in the organization. We believe that dermatologists can and do share many of the core values of ACOs. We have long been focused on disease prevention, and providing

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high quality, cost-effective care is central to most of our practices. Many AADA members, for example, specialize in early detection of melanoma and other skin cancers and treating skin conditions in a low cost, office-based, E/M setting. As a group, we have very high patient satisfaction scores, which we believe to be a very important quality metric. The AADA believes that there is a growing need to look at how both primary care and specialty care are provided and compensated to ensure patients' access to the full spectrum of primary and specialty care. Ultimately, this will guarantee that our patients receive the highest quality care. Although ACOs are largely primary-care centered, specialty care is essential to and can contribute to their success, and efforts must be made to provide viable pathways to integrate non-primary care physicians into the changing care delivery system.

The transition to value-based care presents particular concerns to specialists. Value-based payment models are a way to improve care and control costs by rewarding doctors for quality rather than the number of procedures performed or patients seen. During the transition to a value-based system, there is concern that specialist utilization will be lessened as "decreasing cost" may be confused with "cutting cost" to maximize shared savings. In addition, many dermatologists practice in solo or small practice groups, and because they are small businesses, they need to be able to project income and cash flow needs for overhead. Unfortunately, many of the evolving payment reforms are changing reimbursement too quickly for most specialty physicians to keep up, and there is a need for transitional methodologies, which provide more predictable payment streams and limit financial risk to specialty physicians, particularly those in small practices. The AADA believes there should be greater clarity in physician compensation so that specialists are afforded income predictability and limits to their downside risk, allowing them to develop and maintain sustainable business plans.

Advance Data Analytic Capabilities

Moving toward value-based care requires transforming both business models and care delivery. This dynamic change is dependent on having the appropriate tools in place to deliver better care at lower cost. To accomplish population health management, physicians need an electronic medical records platform that can aggregate both in-network and out-of-network clinical data, as well as cost-of-care data. Specialists need the capability to coordinate their patients' care and manage and report quality metrics for their populations. Engaging in value-based contracts, however, requires a high level of sophistication in data analytic capabilities. Many dermatology practices wish to meet the challenges of the health care environment but have limited resources to invest in needed data infrastructure. Accordingly, the AADA recommends that CMS develop programs that provide greater financial and technical support to assist specialty physicians and others in building necessary, interoperable data analytic capabilities to improve patient care.

Utilize Telemedicine for Shared Savings

The field of dermatology is leading the way on using telemedicine to facilitate care in a cost-effective manner. Current telemedicine systems have not only been shown to improve care by providing near real-time care for lower risk cutaneous disease, they have streamlined specialty care for high risk disease and enabled collaboration between practitioners; ultimately improving the care coordination system. We encourage CMS to incorporate initiatives such as telemedicine into the shared savings payment model to improve engagement of specialists.

Conclusion

The AADA appreciates the opportunity to provide comments on the RFI. We look forward to additional opportunities to comment on these issues and to provide feedback that may help guide policy development.

Please contact Richard Martin, JD, Assistant Director, Regulatory Policy, at (202) 842-3555 or RMartin@aad.org if you require clarification on any of the points or would like more information.

Sincerely,

Dirk M. Elston, MD, FAAD
President, American Academy of Dermatology Association

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American Academy of Family Physicians' Response to the Center for Medicare & Medicaid Innovation's Request for Information: Evolution of ACO Initiatives at CMS

Organization Name:
American Academy of Family Physicians

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Please select the option that best describes you:
Not part of a Medicare ACO or a Commercial ACO

I. Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. Second Request for Applications for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

Based on the feedback from numerous industry experts and family physicians serving in both clinical and administrative roles in ACOs across the nation the American Academy of Family Physicians (AAFP) would posit that likely, many health care organizations may be interested in applying to participate in the Pioneer ACO program. Many have expressed their interest in applying would be dependent on CMS providing further clarity regarding the program and participant outcomes, and on whether or not specific elements of the program were changed in ways that would better support redesign of care and predictability of payment. Key changes that could encourage new Pioneer ACO program participation include:

- Develop an alternative methodology to identify ACO participating providers. The use of tax identification numbers (TIN) to identify participating providers has resulted in significant administrative complexity for ACOs. For example, some ACOs have reported that the use of the TIN has made it significantly challenging to align beneficiaries with individual physicians or even with broader "medical home" care teams. Further, this identification method has failed to create flexibility for individual physicians in deciding whether or not to participate in an ACO. Using the National Provider Identifier (NPI) to identify individual participating providers would be a more effective method.
- Asking beneficiaries to designate their preferred primary care practice, then basing the Pioneer ACO's accountability on the beneficiaries who designated a PCP affiliated with their ACO. CMS allows new Medicare enrollees to designate the ACO as their primary care provider, but does not allow other beneficiaries to do so.

Beneficiaries could still be allowed to change primary care practices at any time.

- Define and clarify the population-based payment/budget amount for the ACO in advance. This clarified projection should incorporate adjustments made based on the health status of the participating beneficiaries and change in Medicare fee schedule amounts.
- Increasing risk-adjusted population-based payment levels in future years based on the Medicare Economic Index (MEI), rather than resetting the baseline after three years which essentially wipes out any benefit to the ACO of the savings achieved during the previous years.
- Defining quality measures and target levels for the ACO in advance, avoiding changes to the quality measures or targets mid-stream, and using the measures to protect against declines in quality rather than attempting to improve quality at the same time as costs are being reduced. Thereby avoiding fragmented priorities for participants.

2. **If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?**

CMS should accept any organization that wishes to participate in its payment models and that meets the conditions of participation, with no restrictions on the number or locations of the organizations. It is inappropriate to give one provider in a community access to a different payment approach and prohibit others in the community from also participating if they wish to do so, and it is inappropriate to allow beneficiaries in some communities to benefit from improved care delivery and prohibit others from doing so.

3. **Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?**

As noted above, several changes that would encourage new Pioneer ACO program participation include:

- Asking beneficiaries to designate their preferred primary care practice, and basing the Pioneer ACO's accountability on the beneficiaries who designated a PCP affiliated with their ACO. CMS allows new Medicare enrollees to designate the ACO as their primary care provider, but does not allow other beneficiaries to do so. Beneficiaries could still be allowed to change primary care practices at any time.
- Defining quality measures and target levels for the ACO in advance, avoiding changes to the quality measures or targets, and using the measures to protect against declines in quality rather than attempting to improve quality at the same time as costs are being reduced. The sense of attempting to meet shifting targets is a key factor in driving participant burnout and disenchantment with CMS' ACO initiatives.

B. **Population-Based Payments:**

1. **Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?**

Ideally, ACOs should be able to select different FFS reduction amounts for different

types of providers as well as for Part A vs. Part B services. In cases where a provider's services are going to be completely redesigned, a 100% population-based payment might be preferable to a mix of FFS and PBP payments, whereas in other cases, 100% FFS payments may be the most appropriate. A standard element of most global payment arrangements is a Division of Financial Responsibility (DOFR), and the provider and payer agree on which specific services the provider will be accountable for and which the payer will retain accountability for. CMS should provide this same flexibility for ACOs.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

ACO participating in any CMS ACO initiative should have the flexibility to receive population-based payments for any provider that is delivering services to the ACO's patients.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

CMS should definitely reconsider this requirement. A Pioneer ACO will have very limited ability to redesign care and generate savings under a pure shared savings model since the underlying payment system is still based on fee for service. However, Pioneer ACOs will have much greater ability to redesign care and achieve savings with true population-based payment. Consequently, the ability or inability to generate savings under shared savings is not an accurate predictor of a Pioneer ACO's ability to manage a population-based payment.

Any requirement for financial reserves should be limited to the minimum amount necessary to ensure that the ACO can cover normal variation in the cost of services delivered by participating providers in between disbursements of the population-based payments. Unnecessarily high requirements for financial reserves will make it more difficult for small provider organizations to participate than for larger organizations.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

The current structure of population-based payments is biased against physician-led ACOs, since the payments only replace the payments made to the providers who are part of the ACO. This means that a Pioneer ACO led by a large health system could receive a large population-based payment in place of both inpatient payments and professional fees, but a Pioneer ACO led by a physician group or IPA could only receive a payment based on professional fees, while the hospitals continue to be paid as they always have. A growing number of physician groups and IPAs have the capability to accept a global payment and pay claims to hospitals and other providers, but they cannot do this under the Pioneer ACO program.

Further, in practice, the methodology for distributing the population-based payments can create new administrative burdens on participating ACOs. Examples of these burdens can include the increased complexity of tracking funds and cash flow, or the potential for decreased payment to the participating providers with the intent to offset any deficits via shared savings distributions.

ACOs that have the ability to pay claims directly should have the ability to obtain a population based payment in place of all fee for service payments to all providers

serving their patients if they wish to do so.

II. Evolution of the ACO Model

A. Transition to Greater Insurance Risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

The goal of the ACO program should be to enable healthcare providers to accept as much *performance* risk as possible, without being forced to take on *insurance* risk. "Insurance risk" is the variation in costs due to the number and types of health problems in a patient population; "performance risk" is the variation in costs due to the way those health problems are treated.

Interpreted literally, the term "capitation with insurance risk" means paying a provider organization a fixed amount per patient without regard to the patients' health status. Medicare does not even do this with Medicare Advantage plans (a Medicare Advantage plan receives a risk-adjusted payment from CMS based on the health characteristics of its members), so it would be an inappropriate way to pay providers.

What CMS should offer ACOs instead is the ability to be paid through a risk-adjusted global payment for all of the providers in the ACO instead of individual fee for service payments from Medicare. The providers would not be taking on true insurance risk, because the payments would be risk adjusted, but the providers would be taking on full performance risk, since all of the services provided to the patients would need to be paid from the pre-defined global payment. For physician-led and primary care-based ACOs there should be a hybrid model wherein the ACO can take on the full performance risk for the services directly provided by the ACO participating providers and establish risk corridors for services the ACO does not directly provide (e.g., services provided in non-participating hospitals or nursing homes).

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

ACOs should not be expected to take on full insurance risk. However, ACOs that are willing to accept performance risk need the ability to redesign *all* aspects of patients' care, including professional services, inpatient services, and medications. Consequently, all or part of the types of services covered by Medicare Parts A, B, and D should be included in the ACO's payment.

3. Are there services that should be carved out of ACO capitation? Why?

Each ACO should have the ability to define specific services that it wants to have included and excluded from a global payment. Because of the dramatically different structures of healthcare markets in different communities, providers in some communities will be able to accept accountability for a smaller range of services than will providers in other communities. If a provider is willing and able to help CMS control a portion of Medicare costs, CMS should support that, rather than CMS taking an "all or nothing" approach.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

In order to truly take accountability for costs, most ACOs will need and want to have the ability to pay non-ACO providers directly, rather than having those providers paid directly by Medicare. Further, ACOs will directly benefit from being able to access the cost and quality data for non-ACO providers whom which they are seeking to align care.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk?

ACOs should not be expected to take on full insurance risk. As in the Medicare Advantage program, ACOs should be allowed to modify cost-sharing requirements for patients to enable more effective coordination of care and encourage use of high-value services.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

ACOs should not be expected to take on full insurance risk. CMS should work with the National Association of Insurance Commissioners to develop a common set of regulations governing ACOs that do not force them to meet the same standards as insurance companies since they would not be taking full insurance risk.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

ACOs should not be expected to take on full insurance risk. Medicare should retain responsibility for enrolling Medicare beneficiaries in the Medicare program and dealing with issues related to insurance coverage, and the ACO should focus on connecting beneficiaries with appropriate providers and services. Although ACOs will need to develop appropriate capabilities for care management, patient education, shared decision-making, etc. in order to be successful, CMS should not attempt to prescribe how these capabilities should be implemented.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

ACOs should not be paid using traditional capitation. ACOs should be paid using a risk-adjusted global payment with appropriate risk corridors, risk exclusions, and risk limits.

The method being used by the Pioneer ACO program to set expenditure benchmarks is highly problematic. ACOs in high-spending regions could slow Medicare spending growth significantly but still not be credited with "savings," while ACOs in low-spending regions can potentially be credited with savings even if they have above-average rates of spending growth. Moreover, the methodology does not adjust for higher-than-average updates in Medicare fees in a region due to geographic adjustment factors or other

region-specific policies.

In theory, using a local benchmark would be fairer than a national benchmark, but the only way to estimate what local spending would have been in the absence of the ACO is to compare it to a comparable population in the local market, and if the ACO is large enough, or if there are multiple ACOs in the market, there may be no "comparable" population.

As more and more providers participate in accountable care arrangements, it will become increasingly difficult for CMS to determine what spending would have been in the absence of those arrangements. Consequently, CMS needs to define a different methodology. For example, ACOs could receive a population-based payment that is based on its expenditures during the prior year, updated by an inflation factor such as the MEI, and adjusted for both changes in the risk profile of the beneficiaries and also adjusted for any changes in Medicare fee schedules. This would give CMS a predictable amount of spending with affordable increases from year to year, and it would also give the ACO a predictable budget to work with.

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

There is no perfect method of risk adjustment. Since many ACOs will likely be participating in performance-based payment contracts with Medicare Advantage plans as well as with CMS, it would make sense for CMS to use a common risk adjustment methodology for both ACOs and Medicare Advantage.

CMS has been experiencing problems with risk adjustment in both Medicare Advantage and ACOs because a patient's risk scores inherently increase once the patient joins one of these programs. Providers in ACOs have both a reason and a mechanism for documenting all of the patient's health issues, rather than merely recording the diagnoses needed to justify the particular services they are billing for at a particular time under the fee for service payment requirements. The solution to this is not to eliminate risk adjustment entirely or to use flawed methods (such as "risk adjusting" based on the prior expenditures on that patient), but rather to modify the risk adjustment methodology to solve the specific problems CMS has been experiencing. Most of the increase in RAF (risk) scores under the HCC methodology likely occurs because patients are being coded for the first time to document conditions that they had long before they entered the ACO or MA program. Rather than allowing these preexisting, but newly documented conditions to increase the patient's RAF score, the patient's baseline RAF score should also be increased using the newly documented but pre-existing conditions. That way, only *new* health problems would actually increase the RAF score and signal the need for a higher payment.

Additionally, another prospective challenge to address in designing the appropriate risk adjustment strategy is in weighing the ability of participating ACOs to deliver high value in primary and secondary prevention for beneficiaries. ACOs should not be penalized because their attributed beneficiaries remain healthy and have delayed onset of those morbidities which increase the risk score.

10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

First, ACOs should not be expected to take on full insurance risk. ACOs should have the flexibility to adjust cost-sharing for patients based on the specific types of care changes the ACO is trying to implement. For example, one fruitful area could be to implement a reduction in Part D costs for medications for the management of specific chronic conditions. If an ACO is focusing on an initiative to help patients with COPD avoid exacerbations, it would likely want to reduce cost-sharing on long-acting bronchodilators and nebulizers.

Ultimately, no single change in benefits will be appropriate, because the needs of Medicare beneficiaries differ from region to region and the opportunities for savings that ACOs will pursue will also differ.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

ACOs should not be expected to take on full insurance risk. Giving an ACO full insurance risk creates an incentive for the ACO to avoid patients with multiple or expensive health conditions. Conversely, paying the ACO on a risk-adjusted basis encourages the ACO to treat sick patients and to find higher-quality, lower-cost approaches to treatment.

Many of the current fraud and abuse rules can be relaxed or waived entirely for ACOs receiving risk-adjusted population-based payments. For example, since population-based payment will not vary based on how many services are delivered or how many procedures are performed, there would no longer be any need to ban self-referrals to physician-owned facilities; in fact, physician-owned facilities could enable more efficient, higher-quality delivery of care by giving the physician direct control over all aspects of the delivery of care.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

ACOs should not be expected to take on full insurance risk. Risk adjusted payments protect the ACO against adverse selection and protect beneficiaries against being excluded from care because of pre-existing conditions.

If ACOs are going to be successful, CMS needs to support them by educating beneficiaries about the value of using a coordinated group of providers. While beneficiaries should have the freedom to change providers when they believe they are receiving poor care, they should be encouraged to use providers who work together.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

ACOs should not be expected to take on full insurance risk. Under any method of paying ACOs, the primary method of aligning beneficiaries to ACOs should be the beneficiary's voluntary designation of that ACO to provide the beneficiary's care (or designation of one of the ACO's primary care providers as the beneficiary's medical home). Claims-based attribution, which is already seriously flawed as an approach, will become increasingly problematic as more providers use flexible payments to deliver care in non-traditional ways. If a patient is getting good care without having to make billable office visits to a physician in an ACO, the ACO should be able to get "credit" for such a patient even if there are no billable visit claims to trigger a claims-based attribution methodology.

B. Integrating Accountability for Medicare Part D Expenditures

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

In many cases, use of medication paid for under Part D can enable a beneficiary to avoid much more expensive services under Part A or Part B, and in other cases, an appropriate set of Part B services can enable a beneficiary to avoid the need for expensive medications under Part D. In other words, an expense under Part D can generate savings in Part A or B, and an expense under Part B can generated savings under Part D. However, if the revenues and costs for Parts A, B, and D are kept segregated, there is no way to achieve these net savings.

Consequently, CMS needs to create a mechanism whereby ACOs can make cost sharing and coverage decisions for pharmaceutical benefits with recognition for the impacts of those decisions on *total* Medicare spending, not just Part D.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

ACOs should not be expected to become pharmaceutical insurance companies merely to enable integration of pharmaceuticals into overall efforts to redesign care.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

ACOs should not be expected to accept full risk for pharmaceutical costs or full risk for

any type of cost. Both the price of pharmaceuticals and the health conditions of beneficiaries are outside the control of an ACO, and they should be treated as insurance risk. Conversely, the types of drugs prescribed to treat a patient's conditions is an appropriate part of the performance risk that ACOs should be expected to manage.

C. Integrating Accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

Depending on the community, the providers who care for the majority of Medicaid recipients may be very different from those who care for the majority of Medicare beneficiaries, so it would not be possible to simply assume that a Medicare ACO would have the same ability to manage care for Medicaid recipients as for Medicare beneficiaries. In particular, maternity care is one of the largest components of healthcare spending in Medicaid, but an almost non-existent component of the Medicare program. A Medicare ACO is most likely to be able to take accountability for Medicaid outcomes for dual-eligible individuals.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

It would be extremely difficult, if not impossible, for an ACO to accept accountability for Medicaid-only beneficiaries if they are "attributed" to the ACO using the same types of rules that CMS is using for Medicare. The fact that so many Medicaid recipients only receive benefits for a limited period of time means that an individual may no longer be on Medicaid by the time they are attributed to a provider. Most Medicaid managed care plans require Medicaid recipients to choose a primary care provider (or assign them to a provider if one is not chosen), and CMS would need to require this for Medicaid ACOs to be successful. For young women on Medicaid, their primary source of care may come from a maternity care provider, and so visits to a maternity care provider should be an option for the attribution or assignment of patients to the ACO as well as visits to a primary care provider.

Similarly, the Medicaid outcomes that an ACO can reasonably accept accountability for are those that are directly related to services the ACO can provide while the Medicaid beneficiary is (a) eligible for Medicaid and (b) receiving care from the ACO's providers.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

States can play several key roles in fostering coordination of care:

- States can use accountable payment models to pay ACOs, not only through the Medicaid program, but also for state employees.

- States can facilitate discussions among providers and payers to agree on common approaches to payment (but not payment amounts) under the state action exemption for antitrust.
- States can ensure that large provider organizations do not refuse to contract for services with smaller ACOs that cannot provide a full range of services themselves.
- States can require that health plans release claims data to an all-payer claims database so that providers can develop plans for multi-payer payment and delivery reforms.
- States can ensure that providers forming ACOs are not subject to unnecessary or burdensome insurance regulations.
- States can control unreasonable pricing or payment arrangements or anti-competitive behavior by health plans or hospitals.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

It is inefficient to expect every ACO to independently develop the capability to merge and analyze multiple sources of claims data. Moreover, requiring this capability will make it more difficult for smaller, physician-led ACOs to participate. CMS should proactively support the efforts of multi-stakeholder Regional Health Improvement Collaboratives to become Qualified Entities, to merge Medicare, commercial, and Medicaid claims and combine them with clinical registry data, and to provide analyses to providers interested in forming ACOs as well as to existing ACOs to help them succeed. In addition to providing timely access to data, CMS needs to provide funding to support the analytic work.

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

For dual eligible individuals, it is inappropriate for the state and CMS to try and calculate and pay "shared savings" separately, since some Medicare expenditures can help avoid a Medicaid expenditure, and vice versa. The only way to create a patient-centered payment approach to support these individuals is for CMS and states to acknowledge that they are each "partial payers" for the patients, and to combine their separate payments into a single, risk-adjusted global payment to the ACO. CMS and the states can then decide how to divide any savings between them, rather than forcing the ACO to do so.

For individuals who are on Medicaid or Medicare but not both, states and CMS can pay the ACO separately for their respective beneficiaries, but they should do so using payment methodologies that are as similar as possible. By doing so, the ACO can make changes in care based on the patients' needs, not based on the source of their payment.

D. Other Approaches for Increasing Accountability

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

If all of the providers in a community come together to manage overall outcomes for the residents of a community, CMS could support that through the same mechanisms it uses to support any other ACO. However, a "community ACO" should be a voluntary effort by the community, it should not be imposed on the providers in a community either directly or indirectly, e.g., by setting minimum thresholds for the number of beneficiaries in an ACO that make it impossible for multiple ACOs to form in a community. In many cases, it will be preferable for beneficiaries to have a choice of ACOs, and CMS should not preclude or discourage that.

Community-based services can be part of what any ACO offers or supports if CMS provides the ACO with a sufficiently large and flexible population-based payment; it is not necessary to have a community-wide ACO for that to be possible.

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

One of the biggest weaknesses of the current shared savings payment system used by CMS to support ACOs is that it does not actually change the underlying fee for service payment system, which makes it difficult for providers to significantly redesign the way they deliver care. Conversely, other CMS initiatives like the Comprehensive Primary Care Initiative, attempt to hold individual providers accountable for the total costs of care for beneficiaries, even though those providers cannot control or even influence all aspects of cost. Consequently, both the ACO program and other CMS payment initiatives would benefit by not only allowing, but encouraging the use of payment reforms for primary care practices, specialists, hospitals, post-acute care providers, etc. inside of ACO payment structures.

For example, CMS could make medical home payments to primary care practices, condition-based payments to specialists, and episode payments to hospitals that are part of an ACO. The overall ACO accountability for total cost would help ensure, for example, that episode payments did not cause more episodes to be delivered, while the shared savings calculation to the ACO would be adjusted to account for any extra payments made to providers in the ACO under the individual payment models and any discounts provided to CMS through the individual payment models. This "layering" of payments to an ACO would be analogous to the way many physician groups, physician IPAs, physician-hospital organizations, and health systems "sub-capitate" portions of an overall capitation payment to subgroups of providers.

CMS should also make other payment models available to ACOs besides the current shared savings model. Although Section 1899 of the Social Security Act is entitled "Shared Savings Program," Section 1899(i) explicitly gives CMS the authority to "use other payment models," including a partial capitation model. These other payment models would likely be more attractive to many physician groups than the pure shared savings model that CMS is currently using.

E. Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

Many other payers already have "ACO" contracts with providers. A key challenge these providers face is obtaining comparable payment reforms from CMS. Even if CMS feels it is improving on commercial ACO contracts when it defines the way that Medicare will contract with ACOs, using a different payment structure or different administrative requirements than other payers means that CMS is creating extra costs and complexity for the ACO and its providers that will reduce their ability to focus on the primary goals of care improvement and cost reduction.

In order to encourage participation by payers that are not currently supporting ACOs, CMS could offer more favorable Medicare requirements or payment terms to ACOs that have multiple payers participating.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

CMS could encourage alignment of quality measurement among payers in several ways.

First, CMS should align its own quality measurement programs. In both its ACO and CPCI programs, CMS has chosen different quality measures than it uses in its Medicare Advantage 5 Star Quality Rating program; this means that Medicare Advantage plans that want to support an ACO or CPCI physician practice typically want to use 5 Star measures instead of or in addition to the CMS measures.

Second, CMS should allow case-by-case changes in the quality measures it requires of individual ACOs in order to align with the measures that commercial and Medicaid payers want to use for those ACOs. It is unreasonable for CMS to expect other payers to adjust their quality measures if CMS is not willing to do so itself.

Finally, CMS should give ACOs the flexibility to propose quality measures that are directly related to the aspects of care delivery where the ACO will be focusing its cost containment efforts. Requiring the ACO to focus on quality improvement for patient conditions or services different from where the ACO is attempting to reduce costs not only forces the ACO to spread its care transformation resources more thinly than would be desirable, it also means that CMS is not measuring quality in the areas where beneficiaries have the most potential to be harmed by cost reduction efforts.

Submission by the American Association for Community Dental Programs in Response to Request for Information: Evolution of ACO Initiatives at CMS

The American Association for Community Dental Programs (AACDP) is pleased to submit for consideration its suggestions under Section II of the RFI, Evolution of the ACO Model.

SUMMARY– Dentistry remains outside the realms of health reform, largely due to the dominance of a private, solo, fee-for-service model for the delivery of care. The current "cottage industry" approach to dentistry is inherently limited and incapable of implementing larger, more sophisticated systems approaches to address dental disease at a population level. The manner in which dental health is financed, organized, and provided must be wholly reconfigured if dental health is to assume its proper role in health reform and delivery. New or alternate initiatives to incorporate dental care in ACOs can accomplish this necessary restructuring.

The AACDP recommends that the evolution of ACO initiatives include new or alternate designs for incorporating dental care into the spectrum of health services offered, so that ACO services can indeed be fully integrated and rightfully termed "comprehensive". These ACO model designs would address two populations: pediatric Medicaid beneficiaries (included under the Affordable Care Act), and Medicare beneficiaries (whose inclusion may require legislation and regulations comparable to the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110-275)). In both cases designs should not merely graft extant fee-for-service dentistry to an ACO. Instead, these new or alternate ACO designs should be consistent with improving oral health status at a lower cost for the enrolled population by establishing criteria for innovations in financing, organization, evaluation, and workforce utilization.

BACKGROUND– A central message of "Oral Health in America: A Report of the Surgeon General" (2000) is "Oral health is integral to general health." Actual realization of that precept faces several obstacles and realities:

- Despite the importance placed on oral health, wide inequities and disparities in health status persist throughout the population.
- Dental disease (here meaning tooth decay and gum disease) is largely preventable. Yet apart from advances in community water fluoridation and molar sealant programs, the delivery of dental care remains focused on restorative and acute care, instead of promoting and providing preventive services on a population basis.

- The place of oral health within the larger context of health reform remains ambiguous, not being formally included as part of "comprehensive primary care" in the Affordable Care Act. Not being conceptually or operationally part of such care, the dictum that "Oral health is integral to general health" is limited.

  [It should be noted that whereas the Affordable Care Act does contain oral health provisions– e.g., extension of Medicaid coverage, inclusion of pediatric dental benefits in health exchanges, expansion of school-based sealant programs– these are largely conventional offerings, and do not address the structure and organization of care. Attempts along these latter lines were obviated when appropriations were denied for Sec. 5304, Alternative Dental Health Care Provider Demonstration Project, and Sec. 5101, National Health Care Workforce Commission under Subtitle B– Innovations in the Health Care Workforce.]

- The existing organization of dental care is restricted to the private, solo, fee-for-service practice model for those able to partake of it. For those whom this model cannot accommodate, there is implicit reliance on the so-called "safety net" of publically supported clinics and programs. No other more suitable organizational models are allowed to address the prevalence and incidence of dental disease which vary with regard to "person, place, and time," i.e. socioeconomic status, geography, age.

ISSUES– The following issues will need to be addressed by initiatives seeking to incorporate dental health as part of a truly comprehensive health reform strategy:

- Use of Federal funding to affect changes in dental care, unlike with medical care through ACOs, at present is limited. Dental coverage is essentially non-existent in the Medicare program, and it can vary in state Medicaid programs with the pediatric population generally being adequately served, whereas the adult population is often left with greatly reduced coverage or none at all. Thus any incentives for ACOs to include dental coverage for these populations will need to include separate consideration to encourage participation.
- The general lack of organization of dental care above the private practitioner level means that concepts of quality, evaluation, and accountability are rudimentary in comparison to medical care more broadly. Similarly, there is a lack of innovation in financing, organizational development and adaptability, workforce development and utilization, and use of technology, meaning integrated electronic health records and teledentistry.
- A fundamental impediment to innovation and evolution in dental care delivery is the states' prerogatives in setting dental practice laws. While there have been some developments in a few states allowing for the creation of mid-level providers of various types – allowing for independent practice at various levels – utilization of the dental workforce, as well as development of larger, more adaptable and responsive organizational models for the delivery of care, are largely circumscribed by state dental associations' control of the political and regulatory mechanisms in their respective states.
- Formalized linkages for exchange of dental and medical professionals for their mutual benefit in caring for patients and developing population-wide approaches to delivery of care is largely ad hoc, if that.

SUGGESTIONS– While the AACDP acknowledges there are considerable obstacles to incorporating dental care into health reform, we see no better means of making health reform truly comprehensive other than by including dental care in the evolution of ACOs. Wide gaps exist between the way dental care is delivered and the way medical care is being delivered; the incentives for bringing dental health into the fold need to be carefully fashioned. The nature of these incentives is fundamentally twofold:

- In addition to greater comprehensiveness of care and the offering of improved care, competitive advantage is to be found for the ACO that offers well-integrated dental care to its patient population.
- Similarly, a properly organized and integrated dental group practice or network would enjoy competitive advantage and access to larger patient population.

  [Additionally, dental care offered through a larger, more sophisticated and flexible organization could allow for the pursuit of new markets, and alliances with other elements of the public health infrastructure.]

As stated earlier, grafting the existing form of dental care delivery into the ACO model will not suffice. Consequently, AACDP suggests that these criteria be incorporated into any incentives and initiatives for the inclusion of dental care in the evolution of ACOs:

1. Dental providers must be a formally organized group.
2. Dental providers must be willing to engage in risk-sharing arrangements.
3. Dental providers must be able to utilize expanded duty mid-level providers, electronic records, and teledentistry.
4. Dental providers must have quality, evaluation, and accountability measures.
5. Dental providers must demonstrate a plan for the control, prevention, and reduction of tooth decay and periodontal disease, and the provision of appropriate care for its population.
6. Dental providers must demonstrate formalized integration with primary health care providers including physicians for continuing education and exchange of information.

These are but early thoughts AACDP is putting forth to address two fundamental shortcomings in American health care, the absence of dental health as part of comprehensive primary care, and the lack of integration of dental care into health care more broadly. Considerable work needs to be done in this area. AACDP would welcome continuing the conversation with CMS Innovation Center staff.

February 28, 2014

Submitted Electronically

Marilyn B. Tavenner
Administrator
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Department of Health and Human Services
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Baltimore, MD 21244–1850

Re: Center for Medicare and Medicaid Innovation Request for Information: Evolution of ACO Initiatives at CMS

Dear Administrator Tavenner:

The American College of Radiology (ACR), representing more than 36,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the Request for Information (RFI) on the evolution of ACO initiatives at CMS.

CMS issued the Request for Information (RFI) to obtain input on policy considerations for the next generation of CMS ACO initiatives. Topics of particular interest include (1) approaches for increasing participation in the current Pioneer ACO Model through a second round of applications, and/or (2) suggestions for new ACO models that encourage greater care integration and financial accountability.

In addition to increasingly aggressive risk arrangements, CMS offers eligible Pioneer ACOs the opportunity to transition from fee-for-service payments to monthly population-based payments to give these organizations more revenue flexibility in determining how to best motivate providers to improve quality of care and reduce costs for their patient populations.

The ACR has grave concerns that the ACO infrastructures have not fully developed during the first two years. Furthermore, most of the ACOs do not yet have the capabilities to provide an insurance product and the market has not yet created sufficient reinsurance for catastrophe. These mechanistic problems along with the persistently challenging distribution of lump sum payment problem lead us to the inevitable conclusion that progressing to higher-risk and more aggressive payment models that

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move away from fee-for-service will be counter to the interests of the systems, the physicians and in turn the patients we serve. We feel that more work needs to be done to articulate this further in our comments below.

Section I. Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes based contracting.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

Considering that initially there were 32 Pioneer ACOs and now there are only 23, the ACR believes that it will be a challenge for CMS to get more organizations to volunteer to contract as new Pioneer ACOs. It has been a challenge for the ACOs to report all of the quality measures required. However, in the future more measures will be needed to help represent the contributions that all participants make in the system to improve quality of care. Also, many ACOs have chosen to continue to participate but only if they can continue in lower-risk arrangements. Therefore, if CMS were to move towards more stringent models requiring ACOs to take on more risk, CMS would likely lose some of the current participating ACOs whose savings are still limited and may experience very limited growth in the amount of Pioneer ACO participation.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

There needs to be more transparency between the ACO and the providers as to how savings or losses are realized and thus how shared savings or losses (if any) are allocated. Given that there is a one year lag on reconciliation, ACR members who work in various Pioneer ACOs know that savings have been realized for 2012 but to date, among our members who are leaders in ACOs, no funds have trickled back to the individuals or providers. It has been one year since those savings were realized. It is not clear from either CMS' Pioneer ACO program or that of the Bundled Payments for Care Improvement Initiative how physicians are recognized and paid for contributing to savings and improved patient care, especially for specialists. If specialists, such as radiologists, are no longer paid on a fee-for-service basis because payments to the ACO are made on a partial or fully capitated basis, they are not sure how they will get paid. There is no confidence on how a capitated amount would be distributed. This unknown is a disincentive for radiologists to take further risk.

We find that retrospective attribution of beneficiaries creates a lot of unknowns and problems such as patients who see specialists as their primary care physician (i.e. cardiologist, OBGYN) and moving populations (i.e. snowbirds). The ACR believes that the only way ACOs have a chance to be stable and successful, especially in a higher-risk model, is to have prospective attribution of beneficiaries. They also need these beneficiaries to be affiliated with that health system year-round. A stable and a predictable base of patients provide a sound foundation of knowns with respect to improved care for the patients but also financial stability for the ACO.

Another problem is the addition and removal of providers within the ACO. There are deadlines on who can be added and deleted from the list of providers. Once this list is submitted to CMS, it's not until a year later that the list can be updated again. Adding a physician can take 15-18 months and is based on the TIN, which is problematic for radiologists. This is administratively intensive, and is a constant flow of paperwork. This is not how medical practice or any business operates. There are naturally going to be physicians who leave a group and new ones that join. This process needs to accommodate these rotations in a less burdensome way.

Section II. Evolution of the ACO Model

CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees).

Transition to greater insurance risk

Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

CMS' questions are being posed at a time when there has been relatively little experience with currently configured ACOs and little or no understanding of their impact on beneficiaries and other stakeholders. More time is needed to evaluate ACO effects on health care expenditures, quality of care, patient experience of care, and many other factors. Premature calls for dramatic expansions in ACO scope and insurance risk are troubling.

Perhaps it is possible for some programs to prosper under a capitated ACO model. However, it is unclear to the ACR which programs would neatly fit and be successful and which would not. For example, it is conceivable that a state Medicaid program would be a good fit for a capitated ACO, especially in those states with a large low-income

population. However, it is of concern whether these state insurance programs can assume higher levels risk or save enough money to sustain a bad year. It is not clear that the type and level of insurance needed to cover the losses truly exists.

Other Approaches for Increasing Accountability

Radiologists provide their services based on referrals. Radiologists have no control over the quantity or purpose of the referrals they receive. Therefore a clinical decision support tool has been developed for radiology to review the referrals that they receive and help educate the referring physicians on what studies would best meet the patient's clinical needs based on our ACR Appropriateness Criteria®. This helps the referring physicians and radiologists to be accountable for the amount and type of imaging studies that are ordered. This type of utilization management and decision support is being used in some ACOs and results over a decade show curtailing of ordering similar to that provided by an RBM[i], improvement in the quality of referrals, translating to better and more efficient care. This is an example of how radiologists and the clinical team can together be more accountable for the cost and proper utilization of imaging in patient care. This accountability should also have a mechanism for it to be measured.

Multi-Payer ACOs

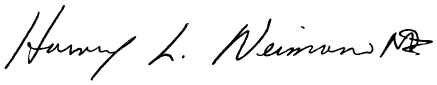
ACOs are complicated to set up and administer. The ACR believes that in order for CMS' ACOs to work in the long run, there needs to be more transparency, consistency on the rules and legalities of how providers are allowed to interact with the ACO and the patients. The rules for CMS differ from the other commercial payers, the arrangements that are acceptable to CMS may not be legal with other payers and interacting with CMS and other commercial payers varies. Moreover, the rules are different from patient to patient and there are legal complications on what can be discussed or shared. The not-for-profit taxes and waivers do not apply across the board; there is a risk when dealing with them. The portfolios are different; one cannot provide uniform care across payers. We believe that CMS needs to consider these complications and consider how ACOs can truly be part of universal health care and a payment system that truly integrates with other payment systems to make the process and care for patients flow as seamlessly as possible.

Conclusion

The ACR feels that CMS has made great strides in developing new payment models and in the development of Accountable Care Organizations. However, we believe that it is too early to push the Pioneer ACOs to take on more risk at this time and move away from using fee-for-service as a major part of their portfolio. There are some basic issues and more groundwork to be prepared in order to establish a sound foundation to take Pioneer ACOs to the next level.

The ACR looks forward to continued dialogue with CMS officials about these and other issues affecting radiology. If you have any questions or comments on this letter or any other issues with respect to radiology or radiation oncology, please contact Pam Kassing at 800-227-5463 ext. 4544 or via email at pkassing@acr.org.

Respectfully Submitted,



Harvey L. Neiman, MD, FACR
Chief Executive Officer

cc: Geraldine McGinty, MD, MBA, FACR, Chair, ACR Commission on Economics
Pam Kassing, ACR
Angela Kim, ACR

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[i] Christopher L Sistrom, Pragya A Dang, Jeffrey B Weilburg, Keith J Dreyer, Daniel I Rosenthal, James H Thrall (2009) Effect of computerized order entry with integrated decision support on the growth of outpatient procedure volumes: seven-year time series analysis., 147-55. In *Radiology* 251 (1).
http://www.ncbi.nlm.nih.gov/pubmed/19...

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February 28, 2014

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Re: CMMI Request for Information: Evolution of ACO Initiatives at CMS

Dear Dr. Conway:

On behalf of the physician and medical student members of the American Medical Association (AMA), we appreciate the opportunity to respond to this Request for Information (RFI) from the Center for Medicare and Medicaid Innovation (CMMI) of the Centers for Medicare & Medicaid Services (CMS). The AMA appreciates CMS' efforts, pursuant to Section 3022 of the Patient Protection and Affordable Care Act (ACA), to evaluate and implement accountable care organizations (ACOs). ACO models can be effective tools to improve quality and coordination of care for patients, reduce the costs of health care, and create a supportive environment for practicing physicians. We offer the following detailed responses to suggest areas of potential improvement in support of the goals of the ACO model, to enhance ACO implementation, and encourage wider participation.

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. Second Request for Applications for the Pioneer ACO Model

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

Many health care organizations are likely to be interested in applying if the details of the program are changed in ways that better support redesign of care and predictability of payment. The AMA particularly believes that restrictive ACO models result in limited participation in ACOs by physician groups. We urge CMS to consider the following improvements as the ACO program moves forward.

For both Pioneer ACOs and ACOs in the Medicare Shared Savings Program (MSSP), CMS should allow beneficiaries to designate their preferred primary care or principal care physician, and base the ACO's accountability on the beneficiaries who designated a physician affiliated with the ACO. CMS allows new Medicare enrollees to designate the ACO as their primary care provider, but does not allow other beneficiaries to do so. Beneficiaries could still be allowed to change physicians at any time. Patient assignment to ACOs should be based on voluntary agreements between patients and their physicians. The core of any successful effort to reduce costs and improve quality in health care is a strong patient-physician relationship. This, in turn, is founded in a voluntary choice by both the patient and physician to begin and maintain that relationship. CMS should encourage and reinforce such voluntary relationships between Medicare beneficiaries and physicians.

The current method for ACO patient assignment puts CMS in the position of deciding which patients and physicians have a relationship, rather than leaving that decision to the physicians and patients themselves. While CMS gives ACOs a list of patients who are **predicted** based on past years' data to be assigned to the ACO, neither the patient nor the physician knows for certain that CMS is assigning accountability to the physician for the costs of all of the patient's care until after retroactive adjustments are made at a much later date. In a dynamic health care system where patients can and do see multiple physicians over the course of a year, it cannot simply be assumed that patients will continue to receive the plurality of their care from the same physician from year to year. The median Medicare beneficiary sees two primary care physicians and five specialists working in four different practices each year. Medicare patients with diabetes typically see eight physicians in five practices. The median beneficiary with cardiac disease sees ten physicians in six practices (Pham et al., *NEJM* 2007). Clearly, it is more fair, effective, and reliable to assign patients to an ACO based on a clear choice by the patient to be part of an ACO physician's panel.

If a beneficiary has maintained a relationship with a particular physician for a number of years or even decades, but does not want to participate in the ACO network, the beneficiary should not be required to switch to a new physician because all of the physician's patients are automatically attributed to the ACO. This would disrupt continuity of care. It could also be extremely detrimental to the physician's practice, which could lose a substantial number of patients who are confused or concerned about what participation in the ACO could mean for their care. The AMA, therefore, urges CMS to allow patients to affirmatively opt out of being part of an ACO while still maintaining their physician of choice.

CMS should hold Pioneer ACOs and ACOs in the MSSP accountable only for those patients who voluntarily choose its physicians to provide or manage their care and allow the ACO to access their data. Patients are currently allowed to opt out of having their data provided to their assigned ACO, but the ACO is not allowed to opt out of accountability for the costs of patients who refuse to share their data. This leaves the physician and ACO in the dark with regard to other services the patient receives outside the ACO. It also creates a disincentive for ACOs to provide primary care services to new Medicare patients with high cost conditions, which can lead to attribution of all of the beneficiary's health care costs to the ACO. ACO assignment without active patient support and participation limits the ability of physicians to help patients improve their health, avoid unnecessary hospitalizations, and reduce the use of unnecessary and duplicative services. An ACO should not be held accountable if a Medicare beneficiary is unwilling or unable to participate in efforts to better coordinate and manage their care. And if a beneficiary and a physician mutually agree to work together, that physician's ACO should benefit from the savings achieved as a consequence of that partnership.

2. **If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?**

CMS should accept any organization that wishes to participate in its payment models and that meets the conditions of participation, with no restrictions on the number or locations of the organizations. It is inappropriate to give one provider in a community access to a different payment approach, and prohibit others in the community from also participating if they wish to do so. It is also inappropriate to allow only certain beneficiaries in a community to benefit from improved care delivery, and prohibit others.

3. **Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?**

CMS should also consider adopting additional improvements that would:

- **Define a population-based payment/budget amount for the ACO in advance**, with adjustments based solely on the health status of the participating beneficiaries and changes in Medicare fee schedule amounts; and
- **Define quality measures and target levels for the ACO in advance**, avoid changes to the quality measures or targets mid-stream, and use the measures to ensure that quality is not decreasing, instead of requiring significant improvements on the quality measures if the primary goal is to reduce costs.

B. Population-Based Payments (PBPs)

1. **Would being able to choose different fee-for-service (FFS) reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?**

Ideally, ACOs should be able to select different FFS reduction amounts for different types of providers as well as for Part A vs. Part B services. In cases where a provider's services are going to be completely redesigned, a 100 percent population-based payment may be preferable to a mix of FFS and PBPs, whereas in other cases, 100 percent FFS payments may be the most appropriate. A standard element of most global payment arrangements is a Division of Financial Responsibility (DOFR) through which the provider and payer agree on which specific services the provider will be accountable for and which the payer will retain accountability for. CMS should provide this same flexibility for ACOs.

2. **Should CMS allow suppliers of durable medical equipment (DME) to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?**

An ACO should have the flexibility to receive PBPs for any provider that is delivering services to the ACO's patients, including DME suppliers.

3. **Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?**

CMS should definitely reconsider this requirement. A Pioneer ACO will have very limited ability to redesign care and generate savings under a pure shared savings model since the underlying payment system is still based on FFS. With true PBP, a Pioneer ACO would have much greater ability to redesign care and achieve savings. Consequently, the ability or inability to generate savings under shared savings is not an accurate predictor of a Pioneer ACO's ability to manage a PBP.

Any requirement for financial reserves should be limited to the minimum amount necessary to ensure that the ACO can cover normal variation in the cost of services delivered by participating providers in between disbursements of the population-based payments. Unnecessarily high requirements for financial reserves will make it more difficult for small provider organizations to participate than for larger organizations.

4. **Should any additional refinements be made to the current Pioneer ACO PBP policy?**

The current structure of PBPs is biased against physician-led ACOs since the payments only replace the payments made to the providers who are part of the ACO. This means that a Pioneer ACO led by a large health system could receive a large PBP in place of both inpatient payments and professional fees, but a Pioneer ACO led by a physician group or IPA could only receive a payment based on professional fees, while the hospitals continue to be paid as they always have. A growing number of physician groups and IPAs have the capability to accept a global payment and pay claims to hospitals and other providers, but they cannot do this under the Pioneer ACO program. ACOs that are able to pay claims directly should also have the option to receive a population based payment in place of all FFS payments to all providers serving their patients, if they wish to do so.

SECTION II: Evolution of the ACO Model

CMS should offer the option for current ACOs in the MSSP to continue in the "Track 1" option with one-sided risk until they are ready to transition to two-sided risk. Under the November 2011 final rule for the ACO program, this option is only available during an ACO's initial three-year agreement period. Then the ACO must shift to "Track 2," with two-sided risk of shared savings and shared losses. ACOs have many concerns about the way the attribution, shared savings, and quality measures are working in the current model, and also concerns about the usability of the data they are receiving from CMS. Extending the Track 1 option could prevent providers from leaving the ACO program altogether until these problems are addressed, as well as encourage new providers to consider entering the ACO program. In addition, CMS needs to make the Advance Payment Model a regular part of the ACO program, rather than a temporary demonstration program. The vast majority of office-based physicians are in practices comprised of fewer than 10 physicians, and they have limited access to capital needed to cover the losses they can experience under fee-for-service payment until shared savings payments are made.

A. Transition to greater insurance risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage (MA) organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

The goal of the ACO program should be to enable health care providers to accept as much *performance* risk as possible, without being forced to take on *insurance* risk. "Insurance risk" is the variation in costs due to the number and types of health problems in a patient population. By contrast, "performance risk" is the variation in costs due to the way those health problems are treated. The term "capitation with insurance risk" literally means paying a provider organization a fixed amount per patient, without regard to the patient's health status. Medicare does not even do this with MA plans. An MA plan receives a risk-adjusted payment from CMS based upon the *health characteristics* of its members. Capitation with insurance risk would be an inappropriate way to pay providers.

CMS should offer ACOs the ability to be paid a risk-adjusted global payment for all of the providers in the ACO instead of individual FFS payments from Medicare. The providers would not be taking on true insurance risk, because the payments would be risk adjusted. But the providers would be taking on full performance risk, since all of the services provided to the patients would need to be paid from the pre-defined global payment.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

No ACO should be expected to take on full insurance risk. However, ACOs which are willing to accept performance risk need the ability to redesign *all* aspects of patients' care, including professional services, inpatient services, post-acute care, and medications. Consequently, all or part of the types of services covered by Medicare Parts A, B, and D should be included in the ACO's payment.

3. Are there services that should be carved out of ACO capitation? Why?

The Affordable Care Act explicitly authorized CMS to offer "partial capitation" and "other payment models" to ACOs, and it should use that authority to do so. Each ACO should have the ability to define specific services that it wants to have included and excluded from a global payment. Because of the dramatically different structures of health care markets in different communities, providers in some communities will be able to accept accountability for a smaller range of services than providers in other communities. If a provider is willing and able to help CMS control a portion of Medicare costs, CMS should support that, rather than taking an "all or nothing" approach.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

In order to truly take accountability for costs, most ACOs will need and want to have the ability to pay non-ACO providers directly, rather than having those providers paid directly by Medicare.

5. **What key elements of the regulatory and compliance framework for MA should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would not be appropriate for ACOs assuming full insurance risk?**

ACOs should not be expected to take on full insurance risk. In order to enable ACOs to accept maximum performance risk, ACOs should have the ability to modify cost-sharing requirements for patients to enable more effective coordination of care and encourage the use of high-value services.

6. **What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?**

ACOs should not be expected to take on full insurance risk. CMS should work with the National Association of Insurance Commissioners to develop a common set of regulations governing ACOs that do not force them to meet the same standards as insurance companies, since the ACOs will not be taking on insurance risk. In regard to the fraud and abuse laws, in general, we believe that the waivers created by the Department of Justice (DOJ) and the Office of Inspector General (OIG) for ACOs that participate in the MSSP should apply to ACO programs developed by CMS. In the event that CMS broadens the scope of risk for ACOs and does not apply the MSSP waivers, CMS should work with stakeholders to develop waivers which will allow ACO innovation. At a minimum, such waivers should be at least as flexible as those developed by the DOJ and the OIG for the MSSP program.

7. **MA organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?**

ACOs should not be expected to take on full insurance risk. Medicare should retain responsibility for enrolling Medicare beneficiaries in the Medicare program and dealing with issues related to insurance coverage, and the ACO should focus on connecting beneficiaries with appropriate providers and services. Although ACOs will need to develop appropriate capabilities for care management, patient education, shared decision-making, etc. in order to be successful, CMS should not attempt to prescribe how these capabilities should be implemented.

8. **What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?**

ACOs should not be paid using traditional capitation. ACOs should be paid using a risk-adjusted global payment with appropriate risk corridors, risk exclusions, and risk limits.

The method being used by the Pioneer ACO program to set expenditure benchmarks is highly problematic. ACOs in high-spending regions could slow Medicare spending growth significantly but still not be credited with "savings," while ACOs in low-spending regions can potentially be credited with savings even if they have above-average rates of spending growth. Moreover, the methodology does not adjust for variations in Medicare payment rates due to geographic adjustment factors or similar payment policies.

In theory, using a local benchmark would be fairer than a national benchmark, but the only way to estimate what local spending would have been in the absence of the ACO is to compare it to a comparable population in the local market, and if the ACO is large enough, or if there are multiple ACOs in the market, there may be no "comparable" population.

As more and more providers participate in accountable care arrangements, it will become increasingly difficult for CMS to determine what spending would have been in the absence of those arrangements. Consequently, CMS needs to define a different methodology. For example, ACOs could receive a population-based payment that is based on its expenditures during the prior year, updated by an inflation factor such as the MEI, and adjusted for both changes in the risk profile of the beneficiaries and also adjusted for any changes in Medicare fee schedules. This would give CMS a predictable amount of spending with affordable increases from year to year, and it would also give the ACO a predictable budget to work with.

9. **What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the MA risk adjustment methodologies.)**

There is no perfect method of risk adjustment. Since many ACOs will likely be participating in performance-based payment contracts with MA plans as well as with CMS, it would make sense for CMS to use a common risk adjustment methodology for both ACOs and MA.

CMS has been experiencing problems with risk adjustment in both MA and ACOs because a patient's risk scores inherently increase once the patient joins one of these programs. Providers in ACOs have both a reason and a mechanism for documenting all of a patient's health issues, rather than merely recording the diagnoses needed to bill for particular services. The solution to this is not to eliminate risk adjustment entirely or to use flawed methods (such as "risk adjusting" based on the prior years' expenditures on that patient). Rather, CMS needs to modify the risk adjustment methodology to address these problems. Most increases in RAF (risk) scores under the Hierarchal Condition Category (HCC) methodology likely occur because for the first time, conditions are being documented that patients had long before they entered the ACO or MA program. These preexisting, but newly documented, conditions should not only increase the patient's RAF score after they join the ACO. That would imply the patient is sicker than they were before they joined. The patient's *baseline* RAF score should *also* be increased using the newly documented but pre-existing conditions. That way, only *new* health problems that occur after the patient joins the ACO would actually increase the RAF score and signal the need for a higher payment. If this change is made, it would then be possible to adopt risk adjustment models that incorporate new data and medical conditions on a rolling basis thereby improving the accuracy of the scoring.

10. **What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?**

ACOs should not be expected to take on full insurance risk. ACOs should have the flexibility to adjust cost-sharing for patients based on the specific types of care changes the ACO is trying to implement. For example, if an ACO is focusing on an initiative to help patients with COPD avoid exacerbations, it would likely want to reduce cost-sharing on long-acting bronchodilators and nebulizers, whereas if the ACO is

focusing on more cost-effective testing for ischemic heart disease, it might want to reduce cost-sharing for tests ordered by physicians who use decision supports and shared decision-making tools based on appropriate use criteria. No single change in benefits will be appropriate, because the needs of Medicare beneficiaries differ from region to region and the opportunities for savings that ACOs will pursue will also differ.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

ACOs should not be expected to take on full insurance risk. Giving an ACO full insurance risk could penalize an ACO that cares for patients with multiple or expensive health conditions. Conversely, paying the ACO on a risk-adjusted basis encourages the ACO to treat sick patients and to find higher-quality, lower-cost approaches to treatment. As we stated in Section II.A.6., the DOJ and the OIG have issued clear guidance for fraud and abuse issues concerning ACOs that participate in the MSSP program. This prospective guidance has become the standard for developing ACOs and, at a minimum, should be applied or closely replicated for CMS ACO programs going forward. In regard to other potential program integrity safeguards, we urge CMS to work closely with stakeholders in developing such safeguards, so as to minimize the burden on physician ACO participants.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in MA that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

ACOs should not be expected to take on full insurance risk. Risk adjusted payments protect the ACO against adverse selection and protect beneficiaries against being excluded from care because of pre-existing conditions.

If ACOs are going to be successful, CMS needs to support them by educating beneficiaries about the value of getting medical care from a coordinated group of physicians and other health providers. While beneficiaries should have the freedom to change physicians or other providers when they believe they are receiving poor care, they should be encouraged to seek care from high quality health care teams.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

ACOs should not be expected to take on full insurance risk. Under any method of paying ACOs, the primary method of aligning beneficiaries to ACOs should be the beneficiary's voluntary designation of a physician associated with an ACO to provide the beneficiary's care (or designation of one of the ACO's primary care providers as the beneficiary's medical home), and designation of the ACO to make sure the beneficiary's care is well coordinated. Claims-based attribution, which is already seriously flawed as an approach, will become increasingly problematic as more physicians and other providers use flexible payments to deliver care in non-traditional ways. If a patient is getting good care without having to make

billable office visits to a physician in an ACO, the ACO should be able to get "credit" for such a patient even if there are no billable visit claims to trigger a claims-based attribution methodology.

B. Integrating Accountability for Medicare Part D Expenditures

1. **Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?**

In many cases, use of medications paid for under Part D can enable a beneficiary to avoid much more expensive services under Part A or Part B. In other cases, an appropriate set of Part B services can enable a beneficiary to avoid the need for expensive medications under Part D. In other words, an expense under Part D can generate savings in Part A or B, and an expense under Part B can generate savings under Part D. However, if the revenues and costs for Parts A, B, and D are kept segregated, there is no way to resolve the true net savings. Consequently, CMS needs to create a mechanism whereby ACOs can make cost sharing and coverage decisions for pharmaceutical benefits with recognition for the impacts of those decisions on all of the related Medicare spending, not just Part D. Similarly, the ACO should be able to get credit for reducing expenditures under Part D, particularly if it requires more expenditures under Part B to do so.

2. **Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?**

ACOs should not be expected to become pharmaceutical insurance companies merely to enable integration of pharmaceuticals into overall efforts to redesign care.

3. **Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?**

ACOs should not be expected to accept full risk for pharmaceutical costs or full risk for any type of cost. Both the price of pharmaceuticals and the health conditions of beneficiaries are outside the control of an ACO, and they should be treated as insurance risk. Conversely, decisions about the types of drugs to prescribe to treat a patient's conditions are an appropriate part of the performance risk that ACOs should be expected to manage.

C. Integrating Accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

Depending on the community, the providers who care for the majority of Medicaid recipients may be very different from those who care for the majority of Medicare beneficiaries, so it would not be possible to simply assume that a Medicare ACO would have the same ability to manage care for Medicaid recipients as for Medicare beneficiaries. In particular, maternity care is one of the largest components of healthcare spending in Medicaid, but an almost non-existent component of the Medicare program. A Medicaid ACO is most likely to be able to take accountability for Medicaid outcomes for dual-eligible individuals.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

It would be extremely difficult, if not impossible, for an ACO to accept accountability for Medicaid-only beneficiaries if they are "attributed" to the ACO using the same types of rules that CMS is using for Medicare. The fact that so many Medicaid recipients only receive benefits for a limited period of time means that an individual may no longer be on Medicaid by the time they are attributed to an ACO. Most Medicaid managed care plans require Medicaid recipients to choose a primary care physician (or assign them if one is not chosen), and CMS would need to require this for Medicaid ACOs to be successful. For young women on Medicaid, their primary source of care may come from a maternity care provider, and so visits to a maternity care provider should be an option for the attribution or assignment of patients to the ACO as well as visits to a primary care provider.

Similarly, the Medicaid outcomes that an ACO can reasonably accept accountability for are those that are directly related to services that the ACO can provide while the Medicaid beneficiary is (a) eligible for Medicaid and (b) receiving care from the ACO's providers.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

States can play a key role in fostering coordination of care and accountability for costs by:

- Using accountable payment models to pay ACOs, not only through the Medicaid program, but also for state employees;
- Facilitating discussions among providers and payers to agree on common approaches to payment;

- Deterring large provider organizations from refusing to provide services under contract to smaller ACOs that cannot provide a full range of services themselves; and
- Ensuring that providers forming ACOs are not subject to unnecessary or burdensome insurance regulations.

4. **What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?**

It is inefficient to expect every ACO to independently develop the capability to merge and analyze multiple sources of claims data. Moreover, requiring this capability will make it more difficult for smaller, physician-led ACOs to participate. CMS should proactively support the efforts of multi-stakeholder Regional Health Improvement Collaboratives to become Qualified Entities, to merge Medicare, commercial, and Medicaid claims and combine them with clinical registry data, and to provide analyses to providers interested in forming ACOs as well as to existing ACOs to help them succeed. In addition to providing timely access to data, CMS needs to provide funding to support the analytic work and to provide technical assistance to physicians.

5. **What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?**

For dual eligible individuals, it is inappropriate for the state and CMS to try and calculate and pay "shared savings" separately, since some Medicare expenditures can help avoid a Medicaid expenditure and vice versa. The only way to create a patient-centered payment approach to support these individuals is for CMS and states to acknowledge that they are each "partial payers" for the patients, and to combine their separate payments into a single, risk-adjusted global payment to the ACO. CMS and the states can then decide how to divide any net savings between them, rather than forcing the ACO to do so.

For individuals who are on Medicaid or Medicare but not both, states and CMS can pay the ACO separately for their respective beneficiaries, but they should do so using payment methodologies that are as similar as possible, so the ACO can make changes in care based on the patients' needs, not based on the source of their payment.

D. Other Approaches for Increasing Accountability

1. **A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be**

considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

If all of the providers in a community come together to manage overall outcomes for the residents of a community, CMS could support that through the same mechanisms it uses to support any other ACO. However, a "community ACO" should be a voluntary effort by the community. It should not be imposed on the providers in a community either directly or indirectly, e.g., by setting minimum thresholds for the number of beneficiaries in an ACO that make it impossible for multiple ACOs to form in a community. In many cases, it will be preferable for beneficiaries to have a choice of ACOs, and CMS should not preclude or discourage that.

In regard to quality measures, "community ACOs" should have the ability to decide which areas of quality improvement they are going to target and the measures they are going to utilize to tackle the quality of care in their community. Each community has different quality improvement needs. Therefore, it should be left up to the discretion of each "community ACO" to decide the quality measures that are most appropriate to address the particular areas that need improvement in that community.

Community-based services can be part of what any ACO offers or supports if CMS provides the ACO with a sufficiently large and flexible population-based payment; it is not necessary to have a community-wide ACO for that to be possible.

2. **In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?**

One of the biggest weaknesses of the current shared savings payment system used by CMS to support ACOs is that it does not actually change the underlying FFS payment system, which makes it difficult for providers to significantly redesign the way they deliver care. Conversely, other CMS initiatives which do make changes in payments, such as the Comprehensive Primary Care Initiative, attempt to hold individual providers accountable for the total costs of care for beneficiaries, even though those providers cannot control or even influence all aspects of cost. Consequently, both the ACO program and other CMS payment initiatives would benefit by not only allowing, but encouraging the use of payment reforms for primary care practices, specialists, hospitals, post-acute care providers, etc. inside of ACO payment structures.

For example, CMS could make medical home payments to primary care practices, condition-based payments to specialists, and episode payments to hospitals that are part of an ACO. The overall ACO accountability for total cost would help ensure, for example, that episode payments did not cause more episodes to be delivered, while the shared savings calculation or the population-based payment for the ACO would be adjusted to account for any extra payments made by CMS to providers in the ACO or any discounts provided to CMS by the ACO as part of the individual payment models. This "layering" of payments to an ACO would be analogous to the way many physician groups, physician IPAs, physician-hospital organizations, and health systems "sub-capitate" portions of an overall capitation payment to subgroups of providers.

CMS should also make other payment models available to ACOs besides the current shared savings model. Although Section 1899 of the Social Security Act is entitled "Shared Savings Program," section 1899(i) explicitly gives CMS the authority to "use other payment models," including a partial capitation model. These other payment models would likely be more attractive to many physician groups than the pure shared savings model that CMS is currently using.

E. Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

Many other payers already have "ACO" contracts with providers. A key challenge these providers face is obtaining comparable payment reforms from CMS. Even if CMS feels it is improving on commercial ACO contracts when it defines the way that Medicare will contract with ACOs, using a different payment structure or different administrative requirements than other payers means that CMS is creating extra costs and complexity for the ACO and its providers that will reduce their ability to focus on the primary goals of care improvement and cost reduction.

In order to encourage participation by payers that are not currently supporting ACOs, CMS could offer more favorable Medicare requirements or payment terms to ACOs that have multiple payers participating.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

CMS could encourage alignment of quality measurement among payers in several ways. First, CMS should align its own quality measurement programs. In both its ACO and CPCI programs, CMS has chosen different quality measures than it uses in its Medicare Advantage 5-Star Quality Rating program; this means that Medicare Advantage plans that want to support an ACO or CPCI physician practice typically want to use 5-Star measures instead of or in addition to the CMS measures for ACOs and its other payment models. Physicians who are part of an ACO should be able to satisfy their Physician Quality Reporting System (PQRS), Meaningful Use Quality Measures, and Value-Based Modifier requirements through their affiliation with an ACO. If the purpose of an ACO is to improve quality and care coordination while reducing costs, then physicians who are taking the steps to align themselves with an ACO should not have to duplicate quality reporting requirements.

Second, CMS should allow case-by-case changes in the quality measures it requires of individual ACOs in order to align with the measures that commercial and Medicaid payers want to use for those ACOs. It is unreasonable for CMS to expect other payers to adjust their quality measures if CMS is not willing to do so itself.

Finally, CMS should give ACOs the flexibility to propose quality measures that are directly related to the aspects of care delivery where the ACO will be focusing its cost containment efforts. Requiring the ACO to focus on quality improvement for patient conditions or services different from where the ACO is attempting to reduce costs not only forces the ACO to spread its care transformation resources more thinly than would be desirable, it also means that CMS is not measuring quality in the areas where beneficiaries have the most potential to be harmed by cost reduction efforts.

ADDITIONAL ISSUES

I. ACO Exclusivity

CMS is applying exclusivity rules for the MSSP more broadly than indicated in the initial regulations, and is effectively precluding any practice that performs evaluation and management services from full-fledged participation in more than one ACO regardless of specialty. As noted in the rule, the goal of this policy is to ensure that only one ACO can claim savings on any given Medicare beneficiary. While the intent is laudable, a growing number of physician organizations have found that the policy is creating significant disruptions in current care networks and physician-patient relationships. This policy has the potential to limit patient choice, and may restrict the number of hospitals and practice networks that physician practices affiliate with. It has also discouraged ACO participation by some large physician group practices. In fact, the Medicare Payment Advisory Commission (MedPAC) has been discussing this issue and seems likely to recommend modifications in the process that CMS now uses.

ACOs participating in the MSSP must provide primary care to at least 5,000 patients. Initially, CMS proposed to define primary care as evaluation and management (E&M) services (not including hospital inpatient or emergency room care) provided by general internists, general practitioners, family physicians and geriatricians. Also, in order to ensure that only one ACO could share in any savings related to these patients, the Tax Identification Number (TIN) used to bill for their care could only be a full-fledged "participant" in one ACO (i.e., all the primary care physicians in a TIN had to be "exclusive" to that ACO unless they created another TIN for the purpose of participating in another ACO).

In the final rule, CMS expanded the attribution process to include a second step where beneficiaries who had not received relevant E&M services from a primary care physician could still be attributed to an ACO based on E&M services provided by another specialty. The rule also specifically stipulated that "each ACO participant TIN *upon which beneficiary assignment is dependent* must be exclusive to one ACO for purposes of the Shared Savings Program" and that "*ACO participant TINs upon which beneficiary assignment is not dependent are not required to be exclusive.*" Because CMS applies exclusivity at the TIN level, however, this means that if even one member of the practice meets the exclusivity requirement, all physicians billing under the same TIN are also exclusive.

Because the vast majority of beneficiaries are assigned based on care from a primary care specialist, this provision was initially expected to have little impact on physicians outside the specialties CMS had designated as primary care. However, in two Frequently Asked Questions (FAQs) posted on the agency's web site, CMS stated that it requires exclusivity whenever any physician in the ACO-affiliated group, regardless of specialty, provides any of the relevant evaluation and management services *even if none of those services were used to attribute patients to the ACO*. CMS also pointed out in the FAQ that physicians do not have to be "participating" in an ACO in order to treat beneficiaries assigned to the ACO. Physicians can get around the exclusivity requirement and participate in multiple ACOs using a different TIN for each one, and they may affiliate with multiple ACOs using a single TIN if they sign up as "other entities" rather than full-fledged "participants." These additional options have some significant downsides, however, such as increased administrative burden and costs.

Together with a number of medical specialties, the AMA has developed a list of possible solutions which we have previously shared with CMS staff and which preferably would apply to both primary care and other specialties. This includes a prioritized list of alternative exclusivity policies from which CMS could choose, along with a list of changes that are needed in whatever final policy, including continuation of the

current one that CMS adopts. It should be noted that movement to prospective assignment would eliminate the need for the more complicated process CMS is now using and could facilitate adoption of a more flexible exclusivity policy.

Our preferred alternative would be to allow participation in multiple ACOs unless the individual physician (as reflected in the NPI) chooses to be exclusive (i.e., the physician would have to opt in to the exclusive arrangement). It would also be possible, though less desirable, to make exclusivity optional at the practice or TIN level.

Whatever exclusivity policy CMS adopts, including retaining the current policy, certain other steps are needed to improve the process. One critical change is to eliminate nursing home visits (HCPCS codes 99304-99318) in skilled nursing facilities (SNFs) from the definition of primary care services. This would correct a policy that misrepresents the type of care that is delivered in SNFs and has exacerbated exclusivity problems for the physicians who practice in this setting. In addition, CMS should provide additional guidance that would help physicians understand the way the attribution process works, when exclusivity to a particular ACO is required, and the potential pros and cons of using an "other entity" arrangement to avoid being locked into a single ACO. Based on feedback from our physicians, we believe that hospitals, ACOs and physicians are all confused about the current rules. We also believe CMS should:

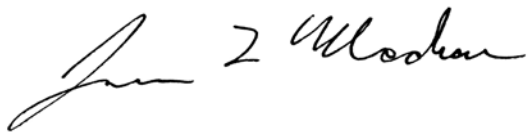
1. Warn hospitals, ACOs and ACO applicants about making false or misleading statements to physicians and patients regarding the consequences of ACO assignment and participation.
2. Provide beneficiaries with a clear statement from Medicare or the ACO that they may continue to receive care from their current physicians whether or not these physicians are part of the ACO.
3. Create an expedited process to help physician practices obtain new TINs and provide "safe harbors" regarding potential Stark, anti-kickback, civil monetary penalties, and Internal Revenue Service liabilities resulting from using multiple TINs.

II. ACO Leadership

As CMS' ACO programs evolve and progress, we urge CMS to ensure that physicians have the opportunity to contribute in a substantial way to the ACO's governance and management activities. For ACOs to achieve the goals of the MSSP and other ACO programs, physician perspectives on matters such as the mission and goals of the ACO, clinical quality improvement, and overall management of patient care activities should be an integral part of ACO leadership activities. In the context of the MSSP, while CMS initially proposed that ACOs be required to have a governance structure specific to the ACO, CMS later finalized a policy that permits hospitals, in some cases, to use their existing governance structure to govern the ACO, providing that they otherwise meet the program specific governance requirements. In our view, this approach can fail, in some cases, to accomplish the level of physician leadership necessary for the long-term success of the ACO. Irrespective of governance model, it is imperative that ACOs develop a functionally integrated leadership model that incorporates physicians into the key decision making processes of the ACO. The AMA and the American Hospital Association recently held a conference which highlighted such integrated leadership models as they currently exist in ten successful delivery systems in the United States. A summary of this conference and these models will soon be available, and can be supplied upon request. We look forward to continuing to work with CMS on this issue as CMS examines best practices for ACOs.

In closing, the AMA appreciates this opportunity to provide our recommendations, and we would be happy to provide additional information and assistance. We look forward to continuing to work with CMMI and CMS to support the successful implementation of ACOs that can benefit the Medicare program, patients, and physicians.

Sincerely,



James L. Madara, MD

February 28, 2014

Re: Request for Information on the Evolution of ACO Initiatives at CMS

AMGA represents multi-specialty medical groups and other organized systems of care, including some of the nation's largest, most prestigious integrated health care delivery systems. AMGA represents 430 medical groups in 49 states that employ nearly 130,000 physicians who treat more than 130 million patients. Our member medical groups are working diligently to provide innovative, patient-centered medical care, while being respectful of Medicare resources. Several of our member medical groups are participants in either the Pioneer Acccountable Care Organization Model (Pioneer ACO) or the Medicare Shared Savings Program in order to further the transformation of health care delivery to a value-based payment system, and we applaud their efforts.

These entities have encountered significant obstacles to their success. We therefore appreciate the opportunity to provide comments on the Request for Information on a potential second round of applications for the Pioneer ACO Model, and other issues related to evolving ACO programs.

Section I-A

CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer Model.

1. **Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?**

   AMGA represents multi-specialty medical groups and other organized systems of care, including some of the nation's largest, most prestigious integrated health care delivery systems. AMGA represents 430 medical groups in 49 states that employ nearly 125,000 physicians who treat over 130 million patients. Our member medical groups are working diligently to provide innovative, patient-centered medical care, while being respectful of Medicare resources.

   The Pioneer model, as it currently exists, will appeal to only those organizations that have a high tolerance for risk, along with and significant capital reserves. Suggestions for retaining current Pioneers, and attracting others, include increasing the transparency around the financial model so that Pioneers are clear about how they are achieving savings or losses. Many AMGA members are concerned about the lack of information regarding the calculation of their financial benchmarks, and request that CMS make this process more transparent, since there is concern that the data may not be completely accurate. Investments that ACOs make in

infrastructure and care process redesign should also be taken into account when determining financial benchmark or when rebasing the benchmarks after the first performance period. Provider organizations must also have confidence that the measures in use are clinically relevant and data extraction for use in benchmarking must be accurate and consistent across all organizations. CMS could appeal to potential future Pioneer applicants if they observed that CMS was making improvements based on the feedback of existing Pioneers, which would thereby promote confidence in the model and encourage broader participation.

2. **If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet qualifying criteria?**

   CMS should limit the number of organizations to those that are most likely to succeed. The small number of Pioneer ACOs has been beneficial to the learning collaboratives, and has promoted transparency. We recommend that CMS increase opportunities for Pioneer ACOs to have learning experiences and to develop relationships with CMMI staff.

3. **Should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the model?**

   CMS should consider ways to encourage low-cost providers to participate in the program. This could be done by allowing ACOs to choose a local or regional benchmark in the financial modeling, not just national data. Such an approach could more appropriately reward providers in all markets by incorporating the differences in regional cost levels into the trend methodology. Several AMGA members have suggested that this approach would accurately reward low-cost providers, and provide greater incentives to remain in the program. It would also encourage others, who have been observers thus far, to become participants. CMS should also consider making their contractors and actuaries available to work with individual ACOs so they will understand how the model, and the changes to it, will play out for them.

   Medical groups and all providers participating in ACO programs have invested significant financial, clinical, operational, and leadership resources to establish sophisticated care management infrastructures and organizational cultures necessary to support the goals of the program. They have done so because it is the right thing to do for their patients and they want to assist CMS to create the new payment models that reward coordinated, patient-centered care with measurable improvements in outcomes. ACOs need a workable financing and operational structure that adequately incentivizes this important work, and we suggest the following additional refinements to the program.

   Beneficiary Attribution/In Network Issue

   Under the current rules, ACOs agree to assume collective responsibility of a defined patient population. Shared savings are based on how ACOs perform on various cost

and quality measures for this population. However, AMGA members have expressed significant concern that the ACO patient attribution methodology does not accurately align patients who have actual encounters in their ACOs, making it difficult for the ACO to manage care appropriately and resulting in inaccurate views of ACO performance. Annual beneficiary turnover may range from 10 to 40 percent, inhibiting the investments ACOs make in programs that have long-term impact, such as care management initiatives. ACOs cannot succeed without understanding who their patients are.

Additionally, allowing beneficiaries to deny, or opt-out, of sharing claims data hampers an ACO's ability to understand the care patients are receiving. It is not unusual for more than 15 percent of beneficiaries to opt out of sharing this data. That effectively means an ACO has an incomplete picture of a large percentage of its patient population. It is difficult, at best, when ACOs are not aware of diagnosis, services, and procedures, a patient receives outside its four walls. Having the complete administrative data picture of the beneficiary is a key piece of the information puzzle for ACOs.

The Pioneer ACO framework places an emphasis on patient engagement, and places the responsibility for this on the ACO, while not permitting ACOs to incentivize their patients to seek care there. The Medicare Payment Advisory Commission (MedPAC) discussed this issue, among other ideas for improving ACOs, at their November, 2013 meeting. Among the ideas discussed was the possibility of incentivizing an ACO's attributed beneficiaries to seek their care in the ACO by permitting lower cost-sharing, or letting the beneficiary share in the savings generated by the ACO, since currently, patients may not understand they are in an ACO, or what that means for them.

MedPAC also compared and contrasted Medicare Advantage (MA) plans and ACOs, concluding that the ability of MA plans to advertise why their plans are attractive to prospective patients, and the requirement that beneficiaries select, and remain, within one MA network for an enrollment period, contribute to the success of these programs. Both of these features are absent from ACO programs in their current form.

In order to understand how "accountable" ACOs truly are, and to address a key issue that serves as a disincentive to enrolling as an ACO, we recommend that beneficiaries should select an ACO for their total care, or at a minimum, identify their primary care provider (PCP), for a defined enrollment period. The designated ACO or PCP could be indicated on the beneficiaries Medicare card. We understand CMS and Congress' sensitivities to beneficiary freedom of choice, however, requiring providers to be accountable, while ignoring the need for accountability on the beneficiary side, provides significant barriers to success in the program.

Timeliness/Quality of Data from CMS

There have been numerous issues surrounding the data ACOs receive from CMS. The timeliness and the utility of data have all been problematic. Some ACOs

received data on their cohort's Hierarchical Condition Categories (HCC) scores more than a year after entering the program. Other ACOs have stated that the quarterly run-up data provided by CMS does not have the level of granularity needed for ACOs to make actionable changes.

The data file structures should be consistent, as well. Otherwise, it becomes necessary to involve the ACO's Information Technology staff to convert the data into a consistent format, and the whole process becomes more resource-intensive and administratively burdensome. Experienced delivery systems are more likely to apply if they have confidence in the claims files content and process, and they look more like formats and processes that are common among other payers. Necessary improvements include the provision of consistent file formats. We believe a joint ACO/CMS/Center for Medicare and Medicaid Innovation (CMMI) committee should be formed that would work on creating a consistent format for data submissions and prioritize requested modifications to the standardized data set. The committee would also focus on other data-related matters such as improving its utility to both ACOs and CMS/CMMI.

Quality Benchmarks/Measures

Another issue of great concern to ACOs is the use of flat percentages for meeting quality benchmarks, rather than empirical data sources. Currently, nearly a third of the 33 quality measure thresholds employ flat percentages, rather than being based on actual Medicare program data. AMGA members have expressed that flat percentages are unattainable, and their continued use harms high-performing ACOs and will discourage future participation in the program.

The measures themselves are not always the best or true indicator of quality care. We believe CMS and ACO providers should work together to develop a measurement set that better reflects the quality of care provided in ACOs.

Fraud/Abuse

ACOs are permitted to utilize waivers that exempt them from possible violations of the Stark self- referral law, the Anti-Kickback Statute, and the Civil Monetary Penalty laws as they restructure healthcare delivery for their patients. We ask that ACOs be able to keep these waivers, along with the efficient delivery of healthcare they afford, after leaving the program, rather than having to unwind such arrangements. Many of the efforts around quality metrics, data gathering, and technology sharing are permissible under waivers, and are activities that should continue even if an ACO departs from the program at some point in the future.

The legal and operational tasks needed to create new arrangements that incentivize improved care delivery are enormous and costly. These system changes are meant to result in improved care at lower cost. Requiring providers to unwind these transactions, in absence of any fraud or abuse activities, after leaving the program, is a significant disincentive to becoming an ACO. Waivers should remain in place so

long as the ACO continues to provide high-quality care as evidenced by satisfying ACO program quality measurements.

Another issue that has to our attention concerns the ability of ACOs to share data derived from CMS claims. For example, let's say an ACO has nearly 2,000 physicians, with some being employed, and some being in different groups across states lines. The health care system has all of these physicians come together to discuss care improvement at certain times throughout the year. It would be beneficial to share de-identified data from CMS claims at these sessions, but sharing is limited to those physicians who are in the ACO, according to the current requirements for Data Use Agreements. We strongly suggest that CMS consider allowing ACO participants to share de-identified claims data openly with all physicians and providers within its broader ACO network, medical staff, or organized system of care so they may engage in a productive dialog about strategies to improvement care management processes. Currently, non-ACO physicians and providers must leave the room when CMS claims data is discussed, and the non-ACO physicians and providers miss out on the benefit of important dialog concerning such things as emergency room visits per 1,000 patients, and the impact of regional variation. Removing this barrier would allow productive discussion on performance improvement activities.

Lastly, AMGA and its member organizations fully support the ACO program. However, we feel financial and operational changes need to be made to allow current and future ACOs to succeed. When viewing the issues that are raised here in a vacuum, they are not fatal to programmatic success. However, when combined, these issues present current ACOs with a difficult path to success and future ACOs with little incentive to enroll. CMS should focus on making the program more attractive to prospective ACOs that may want to participate by removing as many barriers as possible.

Section II-B.

Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes.

1. **What factors, if any, pose barriers to the effectiveness of such collaborations?**

   Some AMGA members are wary of the idea of taking on risk directly by partnering with Part D sponsors due to the volatility in drug markets that would limit their ability to control risk.

   1.A. What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

   ACOs with pharmacies should have the option of developing a "branded" private Part D plan, and offer benefit designs that would not only insure good stewardship of Part D dollars, but also provide opportunities for patient engagement in the ACO by encouraging the use of the ACO's pharmacy. In addition, an ACO should be able to be accountable for Part D without having to be a Part D sponsor itself.

C. Integrating accountability for Medicaid Care Outcomes—as part of the State Innovations Model, CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

1. **CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?**

   ACOs that have patients who are dually-eligible for both Medicare and Medicaid in their aligned population, particularly those who do not have managed care options for this patient population in their state, should have the option of taking full accountability for Medicaid costs and outcomes. This could provide incentives to build more coordinated benefits for those with Medicaid. However, doing so should be an option, and not a requirement, because many ACOs do not have the experience or expertise in being accountable for the full Medicaid benefit, given the different requirements this would entail. The infrastructure required to serve this patient population would be vastly different than what is required for Medicare beneficiaries. The array of necessary services would be geared more toward social support, behavioral health, and transportation.

Thank you for considering our comments. Please contact Karen Ferguson at kferguson@amga.org with any questions you may have.

American Pharmacists Association®
Improving medication use. Advancing patient care.
APhA

March 1, 2014

[Submitted electronically to http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/]

Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Request for Information: Evolution of ACO Initiatives at CMS

Dear Sir/Madam:

APhA is pleased to submit these comments regarding the Center for Medicare & Medicaid Innovation's ("CMMI's") Request for Information ("RFI") related to innovations for accountable care organizations ("ACOs"). Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and the uniformed services.

We thank CMS for the opportunity to comment on new ACO models that encourage greater care integration and financial accountability. APhA considers patient-centered, coordinated care to be the gold standard. Thus, we fully support the transition of the U.S. health system to ACO and other integrated care delivery models that improve outcomes and contain costs. As stated in the RFI, one of CMMI's primary goals is to give providers more tools and resources to improve care outcomes and efficiency. APhA strongly believes that better integration of the Part D prescription drug benefit, especially medication therapy management services ("MTM"), into ACOs is necessary achieve the goal of improved outcomes and efficiency.

Medications play a critical role in the prevention and management of chronic conditions, and the exclusion of Part D medications and related services from Medicare ACOs prevents ACOs from having full oversight over, and coordination of, a significant aspect of patients' health care. In addition, the Part D MTM benefit is siloed and not well coordinated with the clinical services of other health professionals on a patient's health care team. Better integration of MTM services, and the pharmacists who provide them, with the rest of the health care team would help align clinical goals for the patient, better coordinate the care provided, avoid confusion, and ultimately contribute to more efficient and effective care. As demonstrated by the successes in longstanding integrated-care delivery programs like Kaiser Permanente, the Veterans Administration, and Geisinger Health System,

including MTM services delivered by pharmacists as part of team-based care results in improved health outcomes for patients.

APhA strongly advocates the full integration of MTM services and pharmacists into the Medicare ACO infrastructure. Pharmacists are the medication experts of the health care team, and without their participation, ACOs are unlikely to reach their cost and quality goals. While we strongly recommend the full incorporation of pharmacist services into ACO models, at present there are number of barriers to the most full and effective integration. We address these issues below.

I. Pharmacists Are Left Out of the ACO "Care Team"

The inclusion of pharmacists on the care team, including ACO care teams, can have a profound impact on overall quality of care.[1] APhA's member pharmacists who participate in ACOs have indicated to us that the opportunity to work with other health professionals on the care team on a regular basis improves communication and coordination and provides an often missing in-depth focus on medications by the pharmacist that leads to improved care for patients.[2] One member noted that as the pharmacist on the care team, she often caught medication errors and patient adherence issues, resulting in better patient outcomes.

To promote the inclusion of pharmacists in ACOs, APhA supports both integration of pharmacists within the ACO infrastructure (which can be complicated by payment constraints—see Section II below) and contracting between community pharmacies and ACOs. Direct contracting between an ACO and a community pharmacy(ies) may provide additional patient access to services, particularly in rural and underserved areas. Pharmacists practicing in a community pharmacy setting can provide MTM, medication reconciliation, and assistance with care transitions to help manage medication use issues and avoid adverse drug events. We encourage CMMI to explore and implement strategies for integrating medication management services through contracts with community pharmacists and pharmacies.[3]

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[1] *See, e.g.*, Michael E. Porter, Thomas H. Lee, *The Strategy that will Fix Health Care*, HARVARD BUSINESS REVIEW (2013), *available at* http://hbr.org/product/the-strategy-that-will-fix-health-care/an/R1310B-PDF-ENG; C.R. Preslaski , I. Lat, R, MacLaren, J. Poston, *Pharmacist contributions as members of the multidisciplinary ICU team*, CHEST (2013), *available at* http://www.ncbi.nlm.nih.gov/pubmed/24189862; American Diabetes Association,), *Effect of Adding Pharmacists to Primary Care Teams on Blood Pressure Control in Patients with Type 2 Diabetes: A Randomized Controlled Trial*, DIABETES CARE (2010), *available at* http://care.diabetesjournals.org/content/early/2010/10/05/dc10-1294.abstract.

[2] For additional background information on the issue of pharmacist participation in ACOs, we have attached a forthcoming APhA Issue Brief on the Topic. Because this is not yet public, we ask that CMMI treat it as confidential (Addendum 1).

[3] Some ACOs are already contracting with community pharmacies, with good results. UnityPoint's Trinity ACO in Iowa is currently engaged in a project incorporating community pharmacists in its care teams. Under the Trinity model, MTM services will be provided by a team comprised of ACO personnel and pharmacists in participating community pharmacies.

As value-based health care becomes the norm, greater emphasis is placed on meeting quality metrics. Of CMS's thirty-three ACO metrics, twelve are directly related to medications.[4] Alignment of MTM services between Part D and ACOs will allow ACOs to optimize medication use in an efficient and effective manner, which makes practical and financial sense.

II. Payment for Pharmacists Is Not Sufficient in Current ACO Models

Pharmacists have the potential to help ACOs reach their cost and quality goals--yet in discussions with our members who are trying to participate in ACOs, lack of pharmacists' Medicare Part B fee-for-service payment is a barrier, especially in ACOs that have not moved to fully capitated payment systems. For pharmacists embedded in physician office practices, "incident to" billing under Medicare Part B is an option in some cases, but by itself is not sufficient to support a pharmacist's practice. For pharmacists not practicing directly in a physician office practice (i.e., community pharmacists, consultant pharmacists), there are few, if any, payment options to support a pharmacist as part of team-based care in an ACO. The medication management and other services pharmacists can provide improve care quality and patient outcomes, but the current Pioneer ACO payment model not only fails to incentivize pharmacist participation, it creates a substantial barrier to pharmacist inclusion on care teams. We encourage CMS and CMMI to consider payment methodologies that expand opportunities for pharmacists to actively engage in ACOs so that ACOs can capitalize on pharmacists' patient care services, including medication management services.

III. Pharmacists Are Not Included as Providers Under Section 1899 of the Social Security Act

As discussed above, if pharmacists are not included in ACOs and other integrated care delivery models, it will be difficult to reach the goal of fully coordinated care. Because pharmacists are not included in the statutory definition of "ACO Professionals", they are effectively limited from full participation in Medicare ACOs.[5] Thus, Medicare ACOs can make arrangements with pharmacists for their participation in ACOs, but currently pharmacists are not a recognized and required member of the ACO health care team.

Members of Congress have expressed their support for the inclusion of pharmacists in the ACO statute. During the Sustainable Growth Rate discussions of 2013, Senators Grassley (R-IA) and Carper (D-DE) proposed an amendment to "include licensed pharmacists as providers of services in team-based or integrated care activities with one or more of the other defined groups and suppliers", which would have promoted the inclusion of pharmacists in ACOs.[6] Ultimately the amendment was not offered due to time constraints, but the idea has many supporters in the clinical and legislative arenas.

We strongly encourage CMMI to work with CMS to clarify that pharmacists can and should participate in Medicare ACOs. By including pharmacists as part of the patient's health care team,

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[4] For additional information on medication use in ACOs, we have attached APhA's Issue Brief on the topic (Addendum 2).
[5] 42 U.S.C. § 1395jjj(h)(1).
[6] *See* Grassley-Carper Amendment #7 to the Chairman's Mark, http://www.finance.senate.gov/imo/media/doc/SGR%20and%20Medicare%20Beneficiary%20Access%20Improvement%20Act%20Amendments.pdf at p. 84.

patients, communities and the health care system will benefit through better health outcomes, care, and reduced overall health care cost.

IV. Pharmacists Do Not Have the Necessary Access to Electronic Health Records

Pharmacists working in contracted arrangements with ACOs have indicated to APhA that they do not always have optimal access to health information technology ("HIT"). For instance, one group we spoke with does not have full read/write access to patients' electronic health records ("EHR"), and, as a result, is forced to rely on faxes for the transmission of information necessary for MTM services. The faxed information is often incomplete, which makes effective and efficient medication management difficult, especially during care transitions, where lag time and incomplete clinical information can have a profound impact on patient readmissions. Given the considerable focus on HIT upgrades in both the American Recovery and Reinvestment Act of 2009 and the Patient Protection and Affordable Care Act of 2010, reliance on faxes for sharing information with other providers seems antiquated and burdensome. Thus, we recommend that CMMI work with ACOs to ensure that as pharmacists are integrated into care teams, they are provided read/write EHR access, and that, where available, HIT systems integrate pharmacists' medication management services into the patient's overall care record.

It is also important to note that in many cases, pharmacists are told that they cannot have access to EHR systems due to Health Information Portability and Accountability Act ("HIPAA") compliance concerns. This type of information sharing is explicitly covered by HIPAA,[7] so we encourage CMMI to work with the U.S. Department of Health and Human Services ("HHS") to ensure that all providers are well-versed on HIPAA legal requirements so that the information-sharing necessary for effective coordinated care is not compromised.

In conclusion, pharmacists offer many services, including MTM, which improve care quality and patient outcomes in a cost-conscious manner. However, there are currently a number of barriers, including payment, HIT and EHR access, and provider status, to effective integration of pharmacists in ACOs. As CMMI continues to explore new ACO initiatives, we hope you will use APhA as a resource. We look forward to working with CMMI and other ACO stakeholders to find innovative solutions to full and effective care coordination across the entire spectrum of providers and the health system as a whole.

Thank you for the opportunity to provide information on this important issue. If you have any questions or require additional information, please contact Jillanne Schulte, JD, Director of Regulatory Affairs, at jschulte@aphanet.org or by phone at (202) 429-7538.

Sincerely,

Thomas E. Menighan

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs
Anne Burns, Senior Vice President, Professional Affairs

[7] *See* 45 C.F.R. § 164.506.

February 28, 2014

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave., SW
Washington, DC 20201

Dear Administrator Tavenner:

On behalf of the American Telemedicine Association (ATA) and the Telecommunications Industry Association (TIA) we write to urge CMS to make scalable improvements in policies affecting the use of telehealth in alternative payment models. Medicare providers paid under alternative payment methods should have the flexibility to use telehealth as a means to add value for Medicare and its beneficiaries. This would be comparable to the telehealth flexibility for Medicare Advantage plans under Social Security Act section 1852(a)(3)(A). The next step should be Pioneer ACOs, at least pertaining to the "two-sided risk" of Phase II.

Specifically, we request that you waive the Medicare restrictions on telehealth in section 1834(m) for Pioneer ACOs using the Secretary's authority under section 1895(f). Also, we request that for Pioneer ACOs, you waive section 1895(e)(1) regarding home telehealth and remote monitoring for "homebound," section 1895 beneficiaries.

Telehealth should be an integral part of health care delivery reform for Pioneer ACOs. The benefits of telehealth for Medicare beneficiaries and the Medicare program include:

- A reduction of in-person overuse, such as in emergency rooms and preventable inpatient admissions
- Improved triage for faster, appropriate specialist care
- Improved patient outcomes and quality
- Increased provider productivity
- Decreased provider shortages
- A reduction in disparities to patient access
- Decreased unnecessary variations in care
- Improved support care coordination and population health
- Sustained federal investment in EHR/HIE, broadband, and telehealth infrastructure
- A response to beneficiary preference for convenience and satisfaction

It is important to increase the use of Pioneer ACOs. One way to attract participation is to give them advantages over fee-for-service arrangements. One such advantage should be the availability of telehealth means. Telehealth is also a useful tool for meeting the financial objectives of the Pioneer ACO model – and improving beneficiaries' satisfaction.

There is bipartisan interest in Congress for such reasonable and useful improvements. H.R. 3306 includes a statutory change for Medicare's restrictions on telehealth to not apply to all ACOs (under sections 103). Also, the SGR reform agreement includes a provision for the Medicare restrictions to not apply to a forthcoming "alternative payment method" program (under section 2(e)(5) of S. 2000 / H.R. 4015).

The explicit Medicare restrictions on telehealth in 1834(m) are—

- No coverage for about 80% of Medicare beneficiaries who happen to live in the about 1200 metropolitan counties.
- No coverage for "store-and-forward" services (such as transmission of medical images) for the 43 million beneficiaries who live outside of Alaska and Hawaii.
- No coverage for services originating from a beneficiary's home (even for the "homebound"), a hospice and anywhere else from which a beneficiary seeks service.
- No coverage for otherwise covered Medicare services of physical therapy, occupational therapy, speech-language pathology, audiology and some other practitioners.
- No coverage for most health procedure codes, precluding the best judgment of physicians and other practitioners about the medical needs and other circumstances of all Medicare beneficiaries.

Furthermore, there is no permanent coverage in fee-for-service Medicare for remote monitoring of beneficiaries with major, and often multiple, chronic conditions. In particular, home health providers are barred under section 1895(e)(1) from cost-effective uses of telehealth. Under value-based alternative payment methods, providers should be allowed remote patient monitoring and home-based video conferencing services in connection with the provision of home health services (under conditions for which payment for such services would not be made under section 1895 for such services) in a manner that is financially equivalent to the furnishing of a home health visit.

There has been accelerating action among the states to take advantage of telehealth advances, including providing full parity with in-person service coverage. Importantly, CMS has the experience of many state Medicaid plans that are better than Medicare on using telehealth.

Of course, we would welcome the opportunity to work with you and your designees on such timely actions.

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Section I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. The Pioneer ACO Model

Question #3
Other than the options for refining population-based payments outlined in the RFI, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

To increase the number of applicants and have a meaningful impact on improving quality and efficiency, we recommend that the Pioneer Program move beyond an attribution model and adopt a more formal mechanism whereby beneficiaries either elect or are assigned ACO primary care providers and are incentivized to seek care from within the ACO. This level of transparency and mutual commitment will enable more accurate calculations of expenditure benchmarks and make it easier for providers to take on greater degrees of risk, the latter of which is crucial to affecting meaningful change and improved performance.

B. Population-Based Payments

Question #4A
Should any additional refinements be made to the current Pioneer ACO population-based payment policy?

In general, we recommend that CMS look to the commercial market to see how ACOs are evolving, in order to ensure that the Medicare offerings are directionally aligned with the choices being offered in the commercial market.

As indicated earlier, we recommend that the Pioneer Program move beyond an attribution model and adopt a more formal mechanism whereby beneficiaries either elect or are assigned ACO primary care providers and are incentivized to seek care from within the ACO. The ACO model has been successful in stimulating providers to re-engineer their care delivery systems around value. A number of Medicare ACOs have yielded performance results that are better than those of the Medicare fee-for-service program but still fall short of the performance seen in the Medicare Advantage (MA) program. By using a model that relies on benefit design rather than attribution, the MA program has had a meaningful effect on quality and value.

Section II: Evolution of the ACO Model

A. Transition to Greater Insurance Risk

Question #1A

What are the potential benefits and risks to the Medicare program and beneficiaries? (of CMS offering ACOs capitation with insurance risk, similar to Medicare Advantage organizations)

Many providers are relatively new to models that involve acceptance of significant financial risk and are linked to improved condition management and health outcomes. (BCBS FL) Yet a growing portion of providers are embracing these types of models and we believe that downside risk is a necessary component for payment reforms to have a real impact on quality and value. In fact, the opportunity for ACOs to take on full risk already exists today in that a number of ACOs are creating their own MA plans. The MA program already has an extensive regulatory framework and oversight infrastructure in place and can readily function as the vehicle to promote full-risk ACOs. It is not clear that there would be added value to creating a separate program for full-risk ACOs given that they would be functioning as insurance plans and required to meet state laws pertaining to licensure, solvency etc. Moreover, creation of a separate program could create numerous operational implications for CMS as CMS would be responsible for the oversight of these provider groups taking on full insurance risk.

Creating a separate program for full-risk ACOs will create confusion among beneficiaries at the very least. Additionally, if the regulatory framework is not as protective of beneficiaries as the framework that currently exists in the MA program, beneficiaries affiliated with full-risk ACOs could be vulnerable. And, if the financial solvency requirements for full-risk ACOs are not comparable to those for MA plans, the financial integrity of the Medicare program will be at risk.

CMS must adequately assess the readiness of providers in the ACOs to participate in a full-risk model. Those providers not ready to advance to full risk should continue to work towards achieving greater levels of sustainable clinical integration.

Question #2
What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

If ACOs are going to accept full insurance risk, they should be responsible for all categories of spending, similar to MA plans, provided they are subject to all of the same rules and requirements regarding licensure, financial solvency, etc, applicable to MA plans. Responsibility for comparable categories of care within the same regulatory framework will create a level playing field and provide consistent protections for beneficiaries.

Question #3
Are there services that should be carved out of ACO capitation? Why?

No, as stated above, if ACOs are going to accept full insurance risk, then they should be responsible for all categories of spending, similar to MA plans, provided they are subject to all of the same rules and requirements regarding licensure, financial solvency, etc, applicable to MA plans. Providing ACOs special leeway to have categories of spending carved out of a capitation rate will create an unlevel playing field and cause confusion among beneficiaries. Additionally, if ACOs were permitted, for example, to carve Part D drug spending out of their capitation rate, this would significantly reduce the effectiveness of moving ACOs to a full-risk model, since pharmacy data is a valuable resource in identifying opportunities for improvement in both quality and value.

Question #5
What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would NOT be appropriate for ACOs assuming full insurance risk?

ACOs operating with full insurance risk are functioning as insurance plans. As such, a full-risk ACO should comply with the same rules as any insurance plan or MA plan, including licensure, financial and solvency. These rules ensure that the organization possesses the appropriate business, actuarial, information technology, and financial expertise to succeed. Existing regulations, compliance stipulations and other protections, such as marketing and benefit rules, designed to protect beneficiaries, should apply. Any laxity in otherwise applicable standards will create a substantial risk that new, inexperienced, and potentially undercapitalized organizations could fail and result in disruption for beneficiaries.

Question #7
Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have, such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

To be able to manage full insurance risk, ACOs will need to develop an infrastructure designed to support capabilities to do predictive modeling. The capability to predict, understand, measure, and manage risk is essential. This capability should also include expertise in data extraction and analytics so ACOs can conduct the type of population health management necessary to identify gaps in care and opportunities for improvement. These capabilities depend on the receipt of actionable information – the frequency and usability of the data received from CMS will need to be sufficient to promote timely and meaningful analysis. Of note are the results of a recent survey (https://www.naacos.com/pdf/ACOSurveyFinal012114.pdf) of the Medicare Shared Savings Program (MSSP) ACOs by the National Association of ACOs, which reported that respondents overwhelming indicated that the principle

operational challenge they faced pertained to information technology and data issues – namely, data timeliness, data consistency, data processing, and data analytics.

Question #10
What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes?

ACOs accepting full risk should be permitted to offer reduced copayments for services delivered by ACO providers. Transition to full risk models will be challenging if CMS continues to allow beneficiaries to seek care from any provider, including those not participating in the ACO to which they have been attributed, without providing any incentives to remain within the ACO network. While we agree that acceptance of downside risk is essential to promoting the change necessary to have a real impact on care delivery and efficiency, it is hard to see how clinicians would embrace a full risk model without a more formal mechanism to assign beneficiaries to ACO providers and create incentives for beneficiaries to seek care from ACO providers.

Additionally, we support the use of value-based benefit enhancements for in-network services. MA plans are ideally positioned to serve as the testing ground for value-based insurance design (VBID) strategies that encourage value-based care from high-performing providers. We recommend that VBID strategies be tested and implemented in MA before being considered for less-established full-risk ACOs.

Question #13
If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology?

Yes.

Question #13A
What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

As indicated above, we recommend that the attribution model currently used in the Pioneer ACO program be replaced with a benefit design model that entails beneficiaries electing or being assigned to an ACO provider and offers incentives to beneficiaries to seek care from within the ACO. We caution against offering a mixed model in which some beneficiaries voluntarily elect the ACO and others are attributed to the ACO. A mixed model would present additional care management

challenges for the patients and the ACO and could create confusion among patients and within the ACO itself.

Beneficiary election of or assignment to an ACO primary care provider would enable more accurate calculations of expenditure benchmarks, promote better communication and education between the ACO primary care provider and the beneficiary, foster better coordination of care between the ACO primary care provider and other providers treating the beneficiary, and, in general, enhance the ability of the ACO to affect cost and quality by engaging providers and beneficiaries alike.

B. Integrating Accountability for Medicare Part D Expenditures

Question #3A

What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

As mentioned above, if ACOs are going to accept full insurance risk, they should be responsible for all categories of spending and outcomes, including Part D, provided they are subject to all of the same rules and requirements regarding licensure, financial solvency, etc, applicable to MA plans. Responsibility for comparable categories of care within the same regulatory framework will create a level playing field and provide consistent protections for beneficiaries.

To the extent that ACOs remain a shared savings model, CMS may wish to test the inclusion of the drug benefit with certain ACOs that have been successful at improving cost and outcomes with Part A and B benefits. And for those ACOs that do not take on full risk for the drug benefit, there should be other incentives in place to promote efficiency and affordability.

C. Integrating Accountability for Medicaid Care Outcomes

Question #1A

CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes? Why or why not?

Though the two populations are very different, the capabilities needed to be accountable for their outcomes are similar, indicating that, in some circumstances, it may make sense to bring these populations together. However, not all ACOs will be capable of this type of assimilation, and there could be challenges with integrating and using Medicare FFS and Medicaid FFS data to drive improvement. For example, behavioral health and/or pharmacy data is sometimes siloed under the Medicaid program. CMS may wish to explore additional testing related to the integration of

data across the spectrum of Medicaid services with the goal of giving providers the tools necessary to develop the capability to manage care for the Medicaid population before making them accountable for outcomes. For these reasons, we do not recommend that ACOs be required to take on risk for the Medicaid population. If pursued, assumption of risk for Medicaid outcomes in addition to Medicare outcomes should only be accepted on a voluntary basis.

Question #2
What populations should CMS prioritize in integrating accountability for Medicaid outcomes? (For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?)

With respect to prioritization of sub-populations, we expect this will vary based on the respective goals of the states. However, we would caution that there may be unintended consequences of segmenting the Medicaid population related to small numbers issues.

Question #4
What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?

As mentioned above, not all ACOs will be capable of integrating and using Medicare FFS and Medicaid FFS data to drive improvement. The recent survey of the Medicare Shared Savings Program (MSSP) ACOs by the National Association of ACOs reported that respondents overwhelming indicated that the principle operational challenge they faced pertained to information technology and data issues – namely, data timeliness, data consistency, data processing, and data analytics.

Question #5
What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? (Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?)

With respect to the offering of separate or unified shared savings arrangements, we expect this may vary based on the characteristics of the state and the beneficiaries aligned with the ACO. In other words, while it may be difficult to manage separate shared savings arrangement for the same provider, separate arrangements may be necessary in states where an ACO's population crosses state lines.

D. Other Approaches for Increasing Accountability

Question #1
A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?

A provider-led community ACO model may be worth testing, however, it is unclear whether any organizations currently have the capability to undertake this level of accountability. Moreover, rather than limit the testing to provider-centric models, CMS should think more broadly and include community coalitions and other organizations that may also be in a position to manage the care of a geographically aligned population of beneficiaries.

Question #2B
In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined and, if so, what would the most critical features of such a "layered" ACO be and why?

While it may be worth testing various combinations, or layered approaches, there are challenges with making sure that CMS does not double pay for the same improvement and in determining which part of the combination approach was responsible for the improvement. Additionally, the individual layers within a combination approach must be directionally consistent with each other. For example, bundled payments for surgical procedures may result in surgeons performing their procedures more efficiently, but if there aren't incentives to promote appropriate care, then unnecessary, albeit efficient, procedures may be performed.

E. Multi-Payer ACOs

Question #1
CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to

promote multi-payer alignment of payment incentives and quality measurement. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

Regarding alignment of payment incentives, there is an important distinction between being directionally aligned and exactly aligned. Directional alignment may mean encouraging the use of bundled payments for orthopedists. CMS, by its size and leadership role, often creates such directional alignment by orienting providers in a manner that impacts their behavior in other markets as well. It is worth exploring whether there are other ways for CMS to encourage such directional alignment, such as through educational activities about innovative approaches in private markets. But exact alignment – defining the bundle and having all payers use the same bundle – is not an approach to pursue, given the potential antitrust issues this would raise. In addition, it runs the risk of chilling innovation, by imposing burdensome, costly, and locked-in approaches that may prevent innovations that would benefit consumers. CMS should look at what is going on in private markets, with an awareness that market-specific considerations may lead to different needs and innovations, and focus education about innovations as a means of promoting directionally consistent alignment.

Question #2
How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

CMS can promote alignment of quality measures by selecting quality measures for its programs that are aligned with the National Quality Strategy aims and priorities and that either are endorsed by the National Quality Forum or have been tested for validity and reliability. Alignment of a core set of measures used within public programs is essential to promoting consistency and usefulness of information to beneficiaries. An increased level of harmonization among public programs will also help promote alignment with measures used in the private sector. It is important to note, however, that some flexibility should always remain to allow for focus on special needs and priorities.

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Via e-mail

February 28, 2014

Patrick Conway, M.D.
Deputy Administrator for Innovation and Quality and
CMS Chief Medical Officer
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Dr. Conway,

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to respond to the Center for Medicare and Medicaid Innovation's (CMMI) request for information (RFI) on the evolution of accountable care organization (ACO) initiatives. The AAMC represents all 141 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians.

The AAMC supports alternative payment model (APM) programs such as ACO and bundling initiatives. Academic medical centers have been leaders in testing new payment model initiatives. For example, 12 of the 23 Pioneer ACOs have members from AAMC's Council on Teaching Hospitals (COTH). Another 58 COTH members participate in the Medicare Shared Savings Program ACOs. Finally, AAMC is a facilitator-convener for the Bundled Payment for Care Improvement (BPCI) initiative for 14 teaching hospitals.

The RFI seeks feedback on two possible types of ACO expansion: 1) increasing participation in the current Pioneer ACO program, and 2) developing new ACO models in which entities could assume more risk or receive capitated payment. The RFI also seeks feedback on potential new models that CMMI should consider in the future. The AAMC believes that at a minimum, the new programs must:

- Improve patient care while not placing undue administrative burdens on providers, and
- Not jeopardize the critical social missions supported by add-on payments such as indirect medical education (IME) and disproportionate share (DSH), including providing access to care for patients who cannot find care elsewhere.

Providers who elect to implement new payment models, such as ACOs or bundling, have made a strategic and financial commitment to change and improve care. While some ACOs have had success in sharing savings, all ACOs face programmatic and operational challenges. CMMI should make it a priority to improve the current ACOs programs even as it considers developing new models

that expand risk. This letter summarizes the Association's major recommendations related to ACOs. Responses to the specific questions in the RFI are included as an appendix.

Exclude IME/DSH from Calculations in New ACOs

The AAMC supports alternative payment models in general, but opposes expanding any ACO program that includes policy add-on payments (IME and DSH) in the benchmark and savings calculations. Including such add-on payments means that an ACO that is not closely aligned with an academic center could achieve artificial savings simply by steering care from teaching hospitals to non-teaching hospitals. This "savings" is not derived from improved patient health or reflective of efficient care redesign, but merely represents a reduction in add-on payments. IME and DSH payments support critical missions and societal benefits provided by teaching hospitals and safety net providers; the AAMC has long supported excluding these payments from calculations in alternative payment models to ensure that care decisions are based on quality and clinical judgment, and savings achieved through new care models are the result of care improvement, not defunding social missions. Failure to exclude these payments could create a barrier for patients seeking care at academic centers. The AAMC makes the following two recommendations related to add-on payments in ACO expansion:

- Because the current Pioneer ACO program includes IME and DSH payments in the benchmark and savings calculations, the Pioneer ACO program should not be expanded unless IME and DSH payments are excluded from benchmarks for new participants.

- Similarly, new ACO capitated models should also exclude IME and DSH payments from the payment calculation. As with Medicare Advantage, these payments should be made directly to teaching hospitals.

The AAMC understands that this policy is different from the existing Pioneer program and encourages CMMI to consider a continuing exception for the 23 current Pioneer participants. Moving forward, however, IME and DSH need to be excluded from the calculations to avoid creating a systemic incentive to steer patients from appropriate care at academic centers.

Aligning Performance across Multiple Programs

The CMMI RFI asks for feedback on whether to formalize new models that combine various payment and delivery reform models. The AAMC believes providers, as well as patients, can appropriately participate in more than one value-based demonstration as long as the clinical and operational rules are clear. For example, many of the AAMC participants in BPCI are also part of an ACO. Creating a separate model for combinations of demonstration and payment reforms quickly will become unwieldy. Instead of creating new models, the AAMC recommends that CMMI and CMS establish a systematic process to quickly and fairly resolve clinical and operational conflicts in all overlapping programs. Such a process should focus on ways to align financial reconciliation, quality reporting, and beneficiary assignment across the various programs. The Association also recommends that ACO, BPCI and other medical home providers be given the opportunity to test any proposed resolution prior to implementation. With patient continuity and clarity for providers as key

principles, the AAMC is committed to the growth of alternative payment models, and the tighter the coordination, the better for all.

General Recommendations on Expanding Risk

The RFI asks a series of questions about how ACOs can expand risk while still preserving beneficiary freedom of choice. Full capitation would offer a new opportunity within CMS' ACO portfolio. The ability to receive prospective captitated payments would allow participants additional freedom in determining the best use of resources to care for patients and allow funding for critical services not necessarily funded in the traditional fee-for-service payment system, such as care management and telemedicine. However, capitation within fee-for-service Medicare, without the design features of Medicare Advantage, will present critical challenges particularly in terms of engaging beneficiaries to seek care from the capitated ACO and operationally managing the payments. The AAMC interviewed several academic centers, both those that are in ACOs and those that are not, to identify concerns that would need to be addressed in order for ACOs to take on more risk. The following is a summary of the major concerns and potential solutions.

- **Attribution.** Providers taking on additional risk through capitated payments would need to have immediate and accurate information about who is covered and what services they are using. The current claims-based algorithms are not stable enough to do this. At a minimum, the AAMC recommends: (1) a hybrid attribution model with prospective assignment through claims; (2) a mechanism to resolve/reconcile mistakes in the assignment; and (3) the option to supplement the claims attribution with an optional patient enrollment. Merging physician identifiers and tax identification numbers onto the attribution data sets will also facilitate the verification process by providing ACOs with the ability to more quickly identify the appropriate care team for a given patient.

- **Beneficiary engagement.** Beneficiary attribution also affects beneficiary engagement. Allowing beneficiaries to more proactively align themselves with an ACO would help both patient and provider have a common understanding of who the accountable provider is and the benefits of ACO alignment. Under a purely claims-based attribution model, beneficiaries may not be aware of their assignment to an ACO, which limits the providers' ability to explain the ACO and its goals, and delays enactment of beneficiary incentives, such as enhanced case management or home visitations.

- **Beneficiary choice.** CMMI has been very clear that preserving beneficiary choice is one of the three major goals of an ACO model. AAMC supports CMMI's commitment to promoting care coordination, though providers will face considerable challenges in encouraging patients to seek care only within the coordinated environment of the ACO. To meet this challenge, CMS should give ACOs all possible flexibility to manage patient care, including more freedom to develop communication materials for patients. Several ACOs feel constrained by the language requirements of the current ACO program.

- **Prospective Payment Logistics.** If CMMI develops a capitated ACO, it needs to address significant administrative issues related to a prospective payment model. For example, the prospective model in the BPCI (Model 4) is experiencing many administrative and

methodological issues. Model 4 health systems are struggling with the payment to other providers being made before it is clear that the patient is actually eligible for the bundle, the remittance advice is confusing, and the process has demanded that many manual systems be put in place because of the lack of existing systems to track prospective payment accuracy on the part of CMS and institutions. The AAMC continues to work to resolve these issues. CMMI should apply these learnings to any new capitated program.

- **Part D Expansion.** Pharmacy is a critical element of healthcare costs, but several ACOs the AAMC spoke to cautioned about the difficulty of accepting risk for Part D spending. Among the issues identified are: identifying and building relationships with the numerous national Part D vendors; variations in patient formularies and copays; inconsistencies in the number of patients who have Part D coverage; and the lack of a methodology for calculating accurate benchmarks that appropriately adjust for variations in coverage. Before including Part D data, CMMI needs to address the methodological issues and to establish a facilitator role with the pharmacy benefit managers to help the ACOs effectively and efficiently engage the Part D plans.

- **Medicaid Expansion.** The AAMC recommends that any expansion of an ACO to include Medicaid coverage should start with patients who are dually eligible for Medicare and Medicaid. A dual program would provide synergy with current ACO redesign efforts. Any expansion should also coordinate with the various state programs which focus on Medicaid costs, and the various duals programs that are currently being tested.

- **Infrastructure Costs.** One challenge that was repeatedly mentioned in the AAMC interviews is the need for upfront funding to defray the costs for the necessary data and population health infrastructure changes. ACOs spend millions of dollars to make these necessary changes, yet in the current ACO model it takes between 18 to 24 months before any savings can be shared. Infrastructure costs and learning experiences are particularly daunting in markets where providers have very little experience with risk and for providers who serve high proportions of uninsured or underinsured patients. The AAMC encourages CMMI to consider revising its advance payment model ACO to allow safety net providers and similar hospitals the opportunity to get advanced funding and thereby minimize this barrier to participation.

Considerations for Medicare Shared Savings Program (MSSP) ACOs

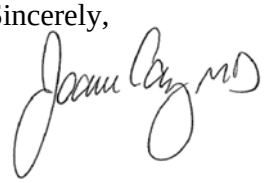
While the RFI focuses on changes CMMI could make to its current and future ACO initiatives, the AAMC believes that a successful suite of ACO offerings from CMS should also include improvements to the Medicare Shared Savings Program. As CMS prepares for the next round of rulemaking, the AAMC makes the following recommendations:

- **Extend the initial contract period from 3 years to 5 years.** It takes time for the new care redesign efforts to develop and for ACOs to see savings from these efforts. ACOs should have at least 5 years to capture these savings before they are rebased.
- **Extend the time period for 1-sided risk.** More and more organizations are entering ACOs and are improving quality and safety. The AAMC is concerned that requiring 2-sided risk too soon may make some ACOs rethink their participation.

- **Improve attribution and data feeds.** The comments on attribution above apply to the MSSP ACO participants as well.
- **Quality Measurement.** Both the Pioneer and MSSP ACOs use the same quality metrics and scoring rules. The benchmarks should be based on accurate data, should reflect real differences and care, and ACOs should have the opportunity to share savings if they improve their quality score.
- **Accurate risk adjustment.** CMS should ensure that the risk adjustment for benchmarks appropriately matches the patient population served. The current ACO program allows the clinical risk score to decrease, but not increase.

The Association appreciates the CMMI's consideration of these important ACO policies. If you have questions, please feel free to contact Mary Wheatley at mwheatley@aamc.org or 202-862-6297.

Sincerely,



Joanne Conroy, M.D.
Chief Health Care Officer

cc: Sean Cavanaugh, CMMI
Hoangmai Pham, CMMI
Ivy Baer, AAMC
Coleen Kivlahan, AAMC
Mary Wheatley, AAMC

Appendix
AAMC responses to selected RFI Questions

This appendix includes excerpts from the RFI and the associated AAMC responses. Please note that fields with a "*" at the end were restricted to 255 characters.

RFI: Evolution of ACO Initiative at CMS
The Centers for Medicare & Medicaid Services (CMS) are seeking input on the following areas related to the evolution of Accountable Care Organization (ACO) initiatives.
1. A second round of applications for the current Pioneer ACO Model
2. New ACO models that encourage greater care integration and financial accountability

Organization Name: Association of American Medical Colleges
Point of Contact: Mary Wheatley
Email: mwheatley@aamc.org
Phone Number: 202-862-6297

Please select the option that best describes you.:

Part of a Medicare ACO
Part of a Commercial ACO
Part of both a Medicare ACO and a Commercial ACO
[X] Not part of a Medicare ACO or a Commercial ACO

****

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters
1. Would additional health care organizations be interested in applying to the Pioneer ACO Model?

Yes
[X] No

1A. Why or why not?*

AAMC has not heard from institutions wanting to become Pioneers. Primary concerns are due to infrastructure costs and the level of risk.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?

[X] Limit the number of selected organizations
Accept all organizations that meet the qualifying criteria

2A. What are the advantages and/or disadvantages of either approach?

The AAMC opposes expansion of the Pioneer ACO model as currently designed. The Pioneer ACO model includes policy payments, such as IME and DSH, in ACO benchmarks

and performance period calculations, giving Pioneer ACOs a significant incentive to steer patients away from hospitals receiving policy payments, even if those settings are the most clinically appropriate. IME and DSH payments support critical missions and societal benefits provided by teaching hospitals and safety net providers; the AAMC has long stated that these payments should be excluded from benchmarks in alternative payment models so that care decisions are based on quality and clinical judgment, and savings achieved through new care models are the result of care improvement, not defunding social missions. The AAMC believes that should the Pioneer ACO model be reopened, add-on payments should be excluded from benchmarks. Current participants in the Pioneer ACO should be excluded from this change in policy.

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Section II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:

- Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;
- Give providers more tools and resources to improve care outcomes and efficiency; and
- Continue to preserve beneficiary freedom of choice in FFS Medicare.

A. Transition to greater insurance risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations?

1A. What are the potential benefits and risks to the Medicare program and beneficiaries?*

Captitated payments provide ACOs the freedom to determine the best resources for Medicare beneficiaries. ACOs will be challenged to incent beneficiaries to use ACO partners who have agreed to the care redesign and coordination strategies.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)*

Additional information on IME/DSH, Part D and Medicaid are discussed below.

3. Are there services that should be carved out of ACO capitation? Why?*

AAMC believes that IME and DSH payments should be excluded from capitated rates and paid normally to teaching hospitals, as is currently done in Medicare Advantage.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

The AAMC believes waivers are critically important for participants in alternative payment models to have flexibility to allow for innovation in care delivery. As providers take on increasing levels of risk, they must also have increased ability to provide the most appropriate care in the most appropriate setting, as well as to better engage patients in their care. At a minimum, participants in a capitated ACO model would require the waivers currently offered to ACOs that allow gainsharing with participating partners (which could include home health, hospice, ambulatory providers, community care managers, as well as inpatient staff) and in-kind beneficiary incentives directly related to care. Additionally, capitated ACOs should be offered the waivers extended to participants in the Bundled Payments for Care Improvement Initiative (BPCI), waiving the requirement for a 3-day inpatient hospital stay prior to the provision of Medicare covered SNF stays; allowing for pre-admission safety visits and post-discharge home visits to non-homebound patients; and waiving the geographic requirement for telehealth. CMS should also consider expanding the beneficiary incentives waiver to give ACOs more flexibility to address social determinants of health for their attributed populations.

8. The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are approaches for setting appropriate capitation rates?

8A. What are the advantages and disadvantages of using national expenditure growth trends? *

8B. What about for using a local reference expenditure growth trend instead?*

CMMI should use an ACO or state or local growth rate to trend forward historical data and to update the benchmark, as this most accurately reflects changes in the local market.

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes?*

AAMC requests additional flexibility in language requirements for ACOs to communicate with patients. See Question 6 for additional information on waivers.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology?

[X] Yes

No

13A. What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?*

Please refer to the AAMC's letter for the Association's complete comments on attribution.

B. Integrating accountability for Medicare Part D Expenditures – An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?

Pharmacy is a critical element of healthcare costs, but several ACOs the AAMC spoke to cautioned about the difficulty of accepting risk for Part D spending. Among the issues identified are: identifying and building relationships with the numerous national Part D vendors; variations in patient formularies and copays inconsistencies in the number of patients who have Part D coverage; and the lack of a methodology for calculating accurate benchmarks that appropriately adjust for variations in coverage for Part D data. Before including Part D data, CMMI needs to address the methodological issues and to establish a facilitator role with the pharmacy benefit managers to help the ACOs effectively and efficiently engage the Part D plans.

1A. What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?*

See question 1 response.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?

Yes
[X] No

2A. Why or why not?*

See challenges noted under question 1.

C. Integrating accountability for Medicaid Care Outcomes – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? (For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they

be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?)

> The AAMC recommends starting such an expansion with patients who are dually eligible for Medicare and Medicaid, as this strategy would provide synergy and focus on the same set of beneficiaries cared for under the current ACO programs. Any expansion should also coordinate with the various state programs which focus on Medicaid costs, and the various duals programs that are currently being tested.

D. Other Approaches for Increasing Accountability – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.
A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns.

2. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?

2B. If so, what would the most critical features of such a "layered" ACO be and why?*

> CMMI should continue to allow providers to participate in multiple initiatives where appropriate. We recommend establishing a transparent infrastructure, with opportunities for broad stakeholder input, to address issues when programs overlap.

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February 28, 2014

BY ELECTRONIC DELIVERY

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Re: Medicare Program Request for Information; Evolution of Accountable Care Organization Initiatives at CMS

Dear Dr. Conway:

The Association of Community Cancer Centers (ACCC) thanks the Centers for Medicare & Medicaid Services (CMS) for this opportunity to comment on the evolution of the Accountable Care Organization (ACO) program.[1]

ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 1900 member institutions and organizations, when combined with our physician membership, treat 60 percent of all U.S. cancer patients.

ACCC applauds CMS's effort to refine the ACO program to ensure the program continues to meet its goals of providing better quality care at lower cost. ACCC believes that community cancer centers can play a vital role in helping ACOs achieve these aims. With this in mind, we encourage CMS to:

[1] http://innovation.cms.gov/Files/x/Pioneer-RFI.pdf.

1. Consider the creation of oncology-centered ACOs under the authority of the Center for Medicare and Medicaid Innovation (CMMI);
2. Institute protections to ensure beneficiaries' access to cancer therapies, if CMS holds ACOs responsible for Part D expenses; and
3. Encourage future development of life-saving cancer treatments by excluding the costs of innovative technologies from the assessment of an ACO's savings and by monitoring access to these technologies.

We discuss these recommendations more fully below.

I. CMS should consider the creation of oncology-centered ACOs under the authority of the CMMI.

CMS's approach to ACOs currently is focused on primary care. CMS uses provision of primary care services to assign beneficiaries to ACOs, and many of the quality measures used to evaluate ACOs assess performance on provision of primary care services. Once a patient is diagnosed with cancer, however, his or her care shifts to oncologists and other specialists. To test the use of ACOs for providing high quality, coordinated cancer care, we recommend that CMS consider the creation of oncology-centered ACOs under the authority of the CMMI. Patients would be assigned to these ACOs based on the care they receive from specialists who most often are involved in treating cancer, including oncologists, hematologists, radiation oncologists, and radiologists. CMS could test new payment models for these ACOs that would encourage better coordination of care for beneficiaries being treated for cancer.

Since the creation of Medicare's ACO program, private payers and providers have entered into oncology-centric ACOs. For example, in Florida, First Coast has created oncology ACOs with two hospitals: Moffitt Cancer Center in Tampa and Baptist Hospital in Miami. CMS could use these programs as models for developing a larger oncology-centric ACO model. ACCC would be happy to meet with CMS to discuss this idea further.

II. If ACOs are held responsible for Part D expenses, CMS should institute protections to ensure beneficiaries' access to cancer therapies.

Beneficiaries fighting cancer should have access to the therapies that are best-suited for their particular type and stage of cancer, as determined by the clinical evidence, not as determined by their effects on the ACO's total costs. Currently, ACOs are not responsible for the expenses of Part D drugs. This could incentivize ACOs to shift patients to Part D therapies although they might not be

the optimal choice for the beneficiary clinically. Moreover, increased cost-sharing under Part D, compared to Part B therapies, could impede beneficiaries' adherence with the prescribed regimen, leading to poor outcomes.

CMS could address these concerns by holding ACOs accountable for Part D expenses, but if it does, it also must implement beneficiary protections. We recommend that, at a minimum, CMS require ACOs to (1) comply with the minimum formulary review and transparency requirements applicable to Part D plans; (2) comply with the current out-of-pocket cost limits under Part D; (3) provide convenient access to drugs by complying with the requirements applicable to Part D sponsors to secure broad participation in pharmacy networks; and (4) protect beneficiaries' choice of providers by allowing out-of-network access to drugs if they choose to receive their prescriptions from pharmacies outside the ACOs. CMS also should monitor ACOs to verify that they do not employ unduly restrictive utilization management techniques that deny or delay access to the most appropriate therapies. These measures will help to balance incentives to control costs with assurances that beneficiaries can receive the cancer therapies they need.

III. CMS should encourage future development of life-saving cancer treatments by excluding the costs of innovative technologies from the assessment of an ACO's savings and by monitoring access to these technologies.

ACCC continues to be concerned about the effect that Medicare's ACO initiatives, including the Medicare Shared Savings Program (MSSP), may have on the future development of innovative cancer treatments. As CMS recognizes, any risk-bearing arrangement increases providers' incentives to minimize costs and therefore discourages use of potentially high-cost treatments that may not have savings that are realized within the relevant time period for measurement of the ACOs' performance. An innovative therapy could cost more during the three-year period of the ACO contract, but could produce better outcomes for the patient and savings for the Medicare program over a longer period of time, however. ACCC believes that CMS should take steps to ensure that its ACO initiatives do not discourage the use of, and therefore reduce the incentive to develop, new treatments that may improve outcomes for cancer patients and substantially reduce costs in the long-run but yet also potentially increase costs in the short-term. CMS may do so by providing additional mechanisms to ensure that access to state-of-the-art care and continued innovation are not hindered by the payment rates and shared savings calculations used in the ACO initiatives.

One such mechanism that ACCC discussed in previous comments to CMS would be a carve-out from the benchmark and performance year expenditures for new technologies that are subject to special payment provisions elsewhere in

Medicare. Under this approach, new technologies that are subject to payment provisions that protect access to innovative care under the Medicare hospital inpatient and outpatient prospective payment systems (PPS) also would be protected under the MSSP. In particular, drugs, biologicals, and devices that are granted pass-through status under the outpatient PPS or technologies that receive add-on payment under the inpatient PPS would be excluded from the shared savings calculations and from any capitated payment rates for ACOs. This exclusion also should apply to these same products used in physician offices, even though the pass-through and inpatient add-on do not apply in the physician office setting. This mechanism would align Medicare incentives for appropriate use of new technologies under the fee-for-service and ACO payment methodologies.

Finally, we recommend that CMS monitor ACOs for changes in beneficiary access to new technologies. CMS should compare access to new technologies for beneficiaries within ACOs to access outside the ACOs to verify that savings are not achieved at the cost of improved care. For cancer care, in particular, CMS also should monitor the timeliness of ACOs' adoption of the most current compendia guidance on use of drugs and biologicals. The statutory provisions on coverage of off-label uses of drugs in anti-cancer chemotherapeutic drug regimens[2] are critical to ensure that Medicare beneficiaries have access to the most appropriate cancer care. If CMS finds that beneficiaries in an ACO have more restricted access to the current standard of care than patients outside the ACO, the agency should take corrective action against the ACO.

IV. Conclusion

ACCC appreciates the opportunity to submit these comments. We look forward to participation from community oncology providers, and we would like to serve as a resource for CMS as you further develop and refine ACOs. Please contact Matthew Farber, at mfarber@accc-cancer.org with any comments or questions. Thank you again for your consideration of these very important issues.

Respectfully,

Virginia T. Vaitones, MSW, OSW-C
President

[2] Social Security Act § 1861(t)(2).

Association of Community Cancer Centers

March 1, 2014

Marilyn Tavenner, R.N.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201
Submitted electronically via PioneerACO@cms.hhs.gov

Re: **Request for Information: Evolution of ACO Initiatives at CMS**

Dear Administrator Tavenner;

athenahealth, Inc. ("athenahealth") appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services ("CMS") in response to its request for information regarding the evolution of Accountable Care Organization ("ACO") initiatives.

athenahealth provides electronic health record ("EHR"), practice management, care coordination, patient communication, data analytics, and related services to physician practices, working with a network of over 50,000 healthcare professionals—a large portion of which are in small, independent practices—serving hundreds of thousands of Medicare beneficiaries in every state. All of our providers access our services on the same instance of continuously-updated, cloud-based software. Our cloud platform affords to us and our clients a significant advantage over traditional, static software-based health IT products as we work to realize our company vision of a national information backbone enabling healthcare to work as it should. Our client's successes, exemplified by a Meaningful Use attestation rate more than double the national average, underscore the very real potential of health IT to improve care delivery and patient outcomes while increasing efficiency and reducing systemic costs. Our cloud platform creates significant advantages in the area of care coordination, making certain core aspects of the next generation of ACO initiatives of particular interest to us and to our care provider clients.

We are generally very supportive of the CMS ACO initiatives that help transition Medicare providers away from fee-for-service and toward more accountable payment models that will reward quality over quantity.

Many large health systems are already participating in that transition. However, the majority of our client providers are small, independent practices that for a number of reasons are unable under current law and regulation to keep pace with the fundamental changes in care delivery and reimbursement attendant to health reform. The next generation of ACO initiatives must address this situation and ensure that these independent practices are empowered, not excluded. These independent providers are essential to the delivery of care to so many Medicare beneficiaries—especially in rural areas.

We respectfully suggest that the following enhancements to ACO initiatives should be considered to significantly bolster the ability of independent providers to succeed in the transition away from fee-for-service reimbursement:

(1) ACO options should be structured with enough breadth and flexibility to ensure that independent providers can participate.

For ACOs to be truly sustainable, they must include all providers, from the solo practitioner to the multi-site, multi-specialty health system. To that end, CMS should recognize that this transition is most difficult, often literally impossible, for small, independent practices that typically do not have the in-house administrative and technical resources to help them manage risk and coordinate care.

Participation in current ACO models requires management by a full team of administrative and business personnel, as well as tremendous technical resources, large patient panels, and data and granular insight into patient data. These inflexible realities leave independent providers with little choice but to accept employment with a hospital or large health system, or forego participation in ACOs. Independent providers are choosing employment at a rapid pace; estimates show that in the past several years up to one-third of physicians have moved from independent practice to employment.[i] Physician employment has been associated with a significant drop in productivity. Hospitals lose $150,000 to $250,000 per year over the first 3 years of employing a physician and must make this up in inpatient revenue.[ii]

This unintended exclusion of independent and small practice care providers from current ACO models has additional, significant negative consequences. The market consolidation attendant to increasing physician employment too often results in net cost increases rather than intended cost reductions. The technology platforms purchased and implemented to coordinate care within de-facto business units established to take advantage of ACOs are too often deliberately designed to impede cross-platform information sharing, resulting in data 'biospheres' that lock in providers and patients, limiting care options and further driving cost increases over time.

To address and correct for those unintended consequences, athenahealth has developed a proposal for a new variety of ACO that we believe fits extremely well within the overall framework of payment reform efforts at CMS. An Independent Risk Manager ("IRM") would enable independent and small group platforms to leverage 21st century information technology to assume and share risk cost-effectively, empowering them to participate in not only ACOs but all payment reform models without forcing them into employment with large groups (which in the rural context is often not an option in the first instance). We have attached our IRM proposal to these comments for your reference, which we presented to staff at the Center for Medicare and Medicaid Innovation ("Innovation Center") in August 2013. We would welcome any opportunity to discuss the IRM model further with you or your staff.

(2) "Meaningful Use" must be truly meaningful for ACOs to succeed.

We support a continued incentive payment for meaningful use of EHRs, to ensure continuation of the significant progress made over the past two years towards EHR adoption and modernization of health information technology. To build on that progress and to transition our health care system toward accountable care, however, Meaningful Use ("MU")—however implemented—must be truly meaningful. This means that disparate vendor platforms must interoperate, sharing information seamlessly in the way that has become routine and expected in the rest of the information economy but remains stubbornly elusive in healthcare. The ACO initiatives will not succeed unless interoperation becomes the norm.

Current MU policy emphasizes adoption and payment of incentive dollars over actual progress toward the supposedly universal goal of interoperability, and in the process may be inadvertently perpetuating the non-interoperable status quo. At athenahealth, we believe that interoperation is an absolute prerequisite for true "meaningful use" of health HIT and, further, that the best way for government to encourage and advance true meaningful use of health IT is by removing existing impediments to interoperability and health information exchange ("HIE") in current policy, regulation, and law. Government rules and actions should be focused on desired outcomes—including actual interoperation between vendor platforms—and less on specific prescriptions as to how those outcomes are to be met.

CMS should focus and realign MU incentives and tighten the definition of "meaningful use" to end de facto government subsidies for technologies that do not (and often cannot) help achieve those goals. Surely no policymakers intended the MU incentives program to subsidize technological dinosaurs with federal dollars, just as nobody intended MU dollars to fund proprietary information silos, locking doctors, patients, and information into closed systems and driving up costs. But both of these unintended consequences are happening, and both are impeding progress toward interoperability. CMS should focus the impact of MU payments by tightening the definition of "meaningful use" to require <u>actual interoperation</u> (an outcome, as opposed to merely theoretical "interoperability") between vendor systems, while avoiding specific prescriptions that could inadvertently hamper innovators as they work to achieve this goal.

Dollars spent on MU incentives is not an accurate measure of success of the MU program; it may, in fact, be exactly the opposite. athenahealth believes in the power of free markets. We do not advocate for government action intended to disadvantage our competitors in the health IT marketplace. If, however, the over-arching goal of federal health IT policy is to spur creation of a framework for true interoperation in healthcare, then at a minimum government should stop subsidizing technologies that either cannot support achievement of that goal or—worse—that deliberately undermine the likelihood of its achievement.

(3) Increase the public availability of CMS claims data and continue to work towards the availability of real-time data for ACOs.

We are encouraged by CMS's recent efforts to increasingly make its treasure trove of data publicly available. This data truly has the potential to transform our health care system, especially when placed in the hands of innovative providers and technology companies. However, the range of permissible uses of CMS data must be broadened to fuel and inform performance improvement. For example, allowing Qualified Entities ("QEs") under the Affordable Care Act to sell non-public data analyses into the health care community will spur innovation and progress toward better care coordination, population health management, and performance improvement.

To maximize the benefit of this expansion of permissible uses, we also suggest the inclusion of unambiguous language in CMS policy to make clear that QE status is not limited—explicitly or implicitly—to non-profit entities. While no explicit non-profit restriction is included in current regulation, HHS regulations and practice evidence a clear bias in favor of non-profits when determining eligibility for QE status. For the expansion of permissible Medicare data uses to produce the innovation and quality improvement desired, CMS must ensure that for-profit companies are permitted also to leverage those expanded uses, with appropriate safeguards against and sanctions for impermissible use or abuse of access to data.

Finally, the data that CMS currently sends to ACOs on a regular basis is essential to the ability of ACOs to understand cost and utilization patterns, which in turn is essential to their success. However, the value of this data to ACO success would increase exponentially if it was provided to ACOs on more of a real-time basis. Especially as CMS works to expand its ACO initiatives to small and independent provider groups, the ability to know when a patient has been in the emergency room, to know about past appointments with other providers during an encounter, or to know about unfilled prescriptions will greatly improve providers' ability to control costs and improve quality. CMS should make the availability of real-time data to ACOs a top priority.

We believe that the payment reform efforts at CMS are on the right path to resolve an issue that has vexed the healthcare community for years. We applaud you and your colleagues for driving this necessary change, and stand ready to assist in this next phase of this effort by answering questions and with whatever additional input we can provide. Thank you again for the opportunity to comment on this important request for information.

Sincerely yours,

Dan Haley
Vice President, Government and Regulatory Affairs

1 Attachment – Independent Risk Manager (IRM) proposal briefing

[i] Accenture, *Clinical Transformation: New Business Models for a New Era in Healthcare,* 2012.

[ii] Robert Kocher, M.D., and Nikhil R. Sahni, B.S., *Hospitals' Race to Employ Physicians: The Logic behind a Money-Losing Proposition,* New England Journal of Medicine 364; 19, 2011.

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IRM: Empowering Independent Practices to Thrive Through Payment Reform

Problem: Participation in Value-based Payment Models Leads to Physician Employment with Large Health Systems, Increased Costs, and Reduced Access to Care

New value-based payment models, such as the Medicare Shared Savings Program under the Affordable Care Act, are meant to encourage new care delivery models to improve quality while decreasing the cost of healthcare. But as implemented those payment models too often incentivize aggressive drives by hospitals and health systems to employ independent physicians, consolidating market share and bringing volume in-house. Most independent physicians want to focus on what motivated them to attend medical school in the first place: caring for patients. While some are perfectly content to become *de facto* business people or employees of large, corporate entities, many prefer to remain autonomous.

The realities of current value-based payment models, however, too often take the choice out of physicians' hands. Participation in these models requires management by a full team of administrative and business personnel, as well as tremendous technical resources, large patient panels, and data and granular insight into patient data. These realities leave independent physicians with little choice but to accept employment with a hospital or large health system, or forego participation in shared savings models. As the healthcare system moves inexorably away from fee-for-service, in truth this is no choice at all; estimates show that in the past several years up to one-third of physicians have moved from independent practice to employment.[i] Physician employment has been associated with a significant drop in productivity. Hospitals lose $150,000 to $250,000 per year over the first 3 years of employing a physician and must make this up in inpatient revenue.[ii] Given the existing shortage of primary care providers, and the relative inelasticity of the nation's physician pool, this will likely ultimately lead to a reduction in access to care.

Furthermore, the law and regulatory guidance gives hospital and health-systems that form Accountable Care Organizations (ACOs) express permission to collectively negotiate contracts with payers on behalf of their members without concern for ordinary antitrust enforcement.[iii] As a result, the animating policy imperatives of care coordination and cost savings that underlie shared savings models are subordinated to the imperative to bring ever-higher volume in-house.

Unlike their health system counterparts, if enabled to participate in shared savings programs, independent physicians will be truly incented to coordinate care with high-value providers, in turn leading to reduced costs and increased quality—and fulfilling the goals of value-based reimbursement models.

Solution: Third Party Independent Risk Managers, To Enable Physicians to Stay Independent and Share Risk, Resulting in Higher Quality and Lower Cost Care

Congress and CMS should support the creation of an Independent Risk Manager (IRM) model, enabling physicians to thrive in value-based payment models without sacrificing their independence, by empowering third parties to relieve them of the administrative and technological burdens of participation in shared savings. An IRM will be an entity that is organizationally independent from healthcare providers and payers, with the IT infrastructure and expertise to provide the risk-pooling, contracting, care coordination, and care management services necessary to manage patient populations that are currently too costly for small physician practices.

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IRM Guiding Principles

Independence: Physicians should be empowered to transition toward value-based payment models while remaining independent if they so choose—including from the constraints of preferred referral relationships that exist within health systems. The IRM model will allow independent physicians to coordinate care along the entire care continuum, regardless of patient or provider health system affiliation.

Accountability: Physicians should be accountable for delivering efficient and high quality care, in value-based reimbursement models, and there should be attainable financial benefits for successfully realizing these objectives. The IRM model will incorporate accountability standards, enabling physicians to make the right decisions clinically and financially, while remaining independent.

Security: To successfully transfer from fee-for-service to a shared savings model while maintaining their independence, physicians must be—and feel—financially secure. Physician employment is on the rise at least in part because the administrative and logistical difficulty of assuming risk has physicians seeking shelter in large groups. To enable physicians who choose to do so to remain independent while holding them to accountability standards, the IRM model will offer physicians security in their financial and clinical ability to transition toward value-based payment models by relieving them of both the administrative burdens and the often-crippling up-front cost to participation in currently-available models.

In furtherance of these guiding principles, an IRM will:

1. Use claims data to identify independent physician practices caring for similar patient populations and convene those practices into networks that can collectively share risk.
2. Facilitate patient-centric clinical integration (information sharing across the care continuum) and care management among networks of physicians to enable successful risk sharing.
3. Provide the quality measurement, benchmarking, and reporting necessary to give networks of physicians and contracting payers insight into how they are performing against value-based reimbursement contracts.

An IRM will also administer a new, unique reimbursement model that specifically allows physicians to assume risk while remaining independent, being held accountable for quality and efficiency, and maintaining the professional security necessary to thrive in a value-based system.

Details: How IRMs Will Operate

1. Use claims data to identify independent primary care physician practices caring for similar patient populations and convene those practices into networks that can collectively share risk.

- IRMs will have access to CMS and private payer claims data for the patients attributed to their participating practices.
- IRMs will gather and analyze claims and other types of clinical and practice management data for participating physician practices to "match" together practices that could successfully share risk.
- IRMs will have qualified staff (data analysts, quality managers, etc.) with expertise in measuring quality, efficiency, effectiveness, and resource use.
- IRMs will be required to comply strictly with all applicable HIPAA data privacy and security requirements.
- IRMs will analyze data to give physician practices a comparison of different reimbursement contracts in which they can choose to participate (such as bundled payments or shared savings).
- IRMs may negotiate these value-based contracts on behalf of providers.

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2. Facilitate patient-centric clinical integration (information sharing across the care continuum) and care management among networks of physicians to enable the utilization management necessary to successfully share risk.

- IRMs will provide patient communication technology, enabling patients to have access to their healthcare information and allowing practices to engage with patients.
- IRMs will provide platforms on which to exchange clinical data across the care continuum.
- IRM analytics will allow practices to understand external costs and utilization across patient populations.
- IRMs will facilitate the selection of the lowest cost and highest quality providers by providing insight at the point of care into downstream and secondary costs, as well as data to help practices reduce overutilization and duplication of services.
- IRMs will provide care management platforms to help providers identify the sickest and most costly patients, enroll those patients in a care management program, and deploy advanced care and disease management solutions.
- IRMs will integrate with electronic health record (EHR) and other health information technology. IRMs will be technology and vendor agnostic, enabling cross-vendor clinical integration and care coordination across participating physicians' EHRs.

3. Provide the quality measurement, benchmarking, and reporting necessary to give networks of physicians insight into their performance against value-based reimbursement contracts.

- The IRM platform will incorporate the quality metrics required by the reimbursement contracts so that the metrics can be tracked and measured in the clinical workflow of the physician practices.
- IRM analytics will allow practices to access a complete picture of quality by benchmarking physician and practice-level performance against peer groups and against targets set by reimbursement contracts.
- The IRM platform will streamline the process of reporting on quality measurements back to payers in accordance with payer requirements.

DETAILS: IRM REIMBURSEMENT MODEL

To maintain the independence, accountability, and security that physicians need, physician reimbursement in the IRM model will have the following characteristics:

- Empowering physicians to remain independent while assuming risk:
    - Physicians' current individual profits and losses will be used as a starting benchmark.
    - As in the ACO model, potential savings will be shared among the IRM risk-sharing pool of providers.
        - Gains will not be strictly shared, but rather will be distributed among IRM providers that realize savings in a given year.
- Holding physicians accountable for delivering efficient and high quality care:
    - Quality and efficiency mechanisms, such as a physician quality metric scorecard, will be used to drive behavior change among participating physicians and to hold physicians accountable to clear outcomes-based targets.
- Providing security to physicians as they assume risk:
    - Revenue will be risk adjusted so that physicians with sicker patient populations do not bear a disproportionate amount of risk.
    - Reinsurance thresholds will be incorporated so that small, independent physician practices do not risk losing their practices as a result of catastrophic patient issues.

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REQUIRED REGULATORY ACTION

Several legal and regulatory changes are needed to enable establishment of the IRM model:

IRM Access to CMS Claims Data

- IRMs must be authorized to access CMS claims data for beneficiaries attributed to the primary care physicians belonging to each IRM.
    - Aggregated claims data will enable IRMs to provide physicians with insight to pool risk and to understand cost and quality among their physician networks.
    - Beneficiary-identifiable data will enable IRMs to provide physicians with insight to understand and act on cost, quality, and utilization at the patient level.
- Beneficiary attribution will be prospective.

IRMs and HIPAA Compliance

- IRMs, and business associates of physician practices, must be explicitly and uniformly required to comply with all applicable HIPAA requirements.
    - Use of participation and data use agreements between IRMs and CMS will bolster existing HIPAA protections.
    - The new HIPAA omnibus rule, released in January 2013 to implement HITECH Act provisions, ensures that Protected Health Information (PHI) is handled appropriately and that strict penalties are enforced for breaches of PHI.
- IRMs will be health services and technology vendors that already have robust HIPAA compliance programs in place.

Stark Laws, Anti-Kickback Statute and Anti-Trust Waivers for IRM Participating Physicians

- Stark, Anti-Kickback Statute (AKS) and anti-trust waivers are needed to alleviate concerns when physicians are sharing savings and maintaining a coordinated referral network.
- It is appropriate to extend these waivers (which already apply in the ACO context) to physicians participating in the IRM payment model since they will be transitioning away from fee-for-service reimbursement and their clinical decisions regarding patient referrals will be driven by the goal of delivering high-quality and well-coordinated care.

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[i] Accenture, *Clinical Transformation: New Business Models for a New Era in Healthcare,* 2012.

[ii] Robert Kocher, M.D., and Nikhil R. Sahni, B.S., *Hospitals' Race to Employ Physicians: The Logic behind a Money-Losing Proposition,* New England Journal of Medicine 364; 19, 2011.

Additional Reading

Molly Gamble, *How Has the Rise of Physician Employment Changed Hospitals' Recruitment Strategies?*, becker's Hospital Review, Nov. 29, 2012. http://www.beckershospitalreview.com/hospital-physician-relationships/how-has-the-rise-of-physician-employment-changed-hospitals-recruitment-strategies.html

References

[iii] Federal Trade Commission and Department of Justice, *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program,* 76 Fed. Reg. 67,025, Oct. 28, 2011.

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

The Pioneer model as it currently exists is most financially attractive to delivery systems that are relatively high cost in their market, in relatively low trend markets, with little seasonal movement of patients. Healthcare organizations in different markets or market positions are not likely to apply under the current model. Now that there is better understanding about how the financial model plays out, organizations that have a beneficial market/national position will be more likely to apply – and over time there will be fewer in this category as early savings are captured.

Because of the volatility and unpredictability of the financial model, only organizations that have a high tolerance for business risk and significant capital reserves are likely to join. The business risk in the Pioneer model goes beyond the financial (shared savings/loss) risk that an ACO may take on in any type of global budget or payer contract. The more significant risks lie in the uncertainty and volatility of the unusual and changing benchmark-setting methodology, and the incomplete data (in particular the missing opt-out and substance abuse claims).

Should CMS implement recommendations around the financial model that make it more attractive to different markets/systems, and reduce volatility, others are likely to apply. In addition, more of the current Pioneers are likely to stay in the program if CMS can increase transparency and predictability of the model, and make it more clear why Pioneers are achieving savings or loss. Such recommendations follow below.

Another way to address the volatility and uncertainty in the model is to move from an annual settlement period to a three-year settlement period. While interim settlements could be made to pay out savings/loss on an annual basis, full risk/final settlement would be on the total three year performance. This would more closely match how many Pioneers are approaching the work – as foundational for long-term success – and encourage those who may not perform well financially in the first year to know that future success could balance early investments.

One other real barrier to adoption – especially to ACOs that serve a high proportion of patients with Behavioral Health needs – is the lack of claims data related to Behavioral Health services. We believe that CMS is taking an overly conservative approach to blinding claims related to behavioral health services, as we and RTI discovered when we worked together to tie out our claims to the CMS quarterly report. Our collective original understanding was that specific substance abuse treatment claims would be withheld for privacy reasons, but a much broader set of claims is in fact being withheld. CMS is the only payer of ours which withholds claims sets for services for which we are accountable – for all other payers where we have outcomes based contracts, we get the full claims set for services for which we are at risk, and we will not enter into a risk agreements on those services without complete claims. We recommend that CMS

reconsider the Behavioral Health privacy issue so that data matches accountability. This would also be beneficial to better coordinating care for our highest risk patients, as many recent published analyses show a high correlation between Behavioral Health diagnosis and high risk.

The Pioneer quality measurement program can be either an attraction or a deterrent for potential Pioneer applicants. CMS has a potentially transformative role when it sets uniform quality standards for a broad group of metrics for a large number of organizations dispersed across the country. It can be very powerful for any provider organization to know that they are being measured consistently and transparently against other advanced healthcare delivery systems. ACO quality measurement has the potential to jumpstart the discussion of what is best in class, who has achieved it, and how can those solutions be spread.

However, provider organizations must have confidence that measures are clinically relevant and benchmarks reflect true best-in-class. In particular, data extraction for use in benchmarking must be accurate and consistent across all organizations via a transparent audit trail, with a statistical methodology open to validation by all participants and outside parties. It is reasonable to assume that Pioneers with advanced quality reporting programs would be reluctant to be part of a quality reporting program that seems under-developed (as compared to HEDIS for example) and could result in publicly reported results that are significantly different from long-time reported and validated outcomes.

If potential Pioneer applicants see that CMS is making noticeable improvements based on feedback from existing Pioneers, this would promote confidence in the model and encourage broader adoption of the ACO measures by other payers.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

   We believe that CMS should select organizations that have likelihood of success, because of the high stakes nature of the program. The small number of the Pioneer model participants has been beneficial to the learning collaborative, and promotes transparency; a significantly larger pool of Pioneers could dilute this positive development. We would like to see an increase in the collaborative learning opportunities and the relationships with CMMI. Once the program is more mature, it would make sense to broaden the number of participants to increase research and modelling opportunities.

3. **Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?**

1. Rewarding Low Cost Providers

   We recommend that CMS change the benchmark methodology to include reward for low cost providers. The Pioneer benchmark methodology appears to favor ACOs with relatively high historical costs, with less or little reward for Pioneers who are low cost providers – good stewards of the Medicare dollar -- in their market, and are delivering and coordinating care in a way that improves outcomes.

   To encourage low cost providers, the benchmark could include a market level component (as it now has a historical cost component and a trend component). With this refinement, low cost providers are not left having to beat their own good performance. It is our understanding that delivery systems which are already low cost declined to apply or participate in the initial implementation for this reason. Without change, that will only continue.

   Use of a local or regional trend could more appropriately budget and reward providers, but even more importantly, would incorporate differences in regional cost levels into the trend methodology.

   Rewarding low cost providers is not just important to attracting new Pioneer applicants, but also to keeping existing Pioneers in the program, both those who are still working to earn savings – giving them further incentive to stay in – and those who have already earned savings, giving them an incentive to stay in despite the uncertainty.

   Including savings in rebasing as is currently being suggested will only widen the gap between low and high cost providers – we strongly recommend this not be included in the financial model. If the intent of including savings in rebasing is to allow Pioneers to recapture their investments, some other methodology should be employed (eg across the board recognition of care management investment, rather than only for those who achieved savings).

   Because rebasing has not yet been tested, it introduces significant risk and unknowns. We recommend that CMS model a number of different financial approached to updating the baseline.

2. Simplifying the financial model.

   The methodology for accounting for decedent costs and mortality rate is highly complex and a significant driver of volatility and uncertainty in the model. As we move further from the baseline period, these problematic features of the multi-variable model only become more pronounced. A more transparent, less complex financial model should reduce risk for ACOs and therefore attract more, and more varied, applicants (eg those who do not have health plans or other easy access to actuarial services).

   We strongly recommend using more standard industry models such as HCC risk adjustment to set the benchmark. Tremendous business risk has been introduced in the Pioneer model because of the unusual, historical cost approach to benchmark setting. Moving to a tested model based on HCC risk, though imperfect, would address most of the uncertainty in the current model, and make the model more transparent, certain and reliable. Using regional

rather than national trends will also attract more applicants, as such an approach will more appropriately budget and reward providers in varied markets.

If CMS maintains the current underlying model, it needs to make the Pioneer model contractors, analysts and actuaries available to work closely with individual ACOs to understand how the model – and changes to it -- play out for the ACO, in their market. This would need to be a built in as a regular component of the program so that Pioneers who do not have a team of actuaries can continue to participate.

3. Refinements to Alignment

There are some components of the alignment methodology that could be amended to attract more applicants. Today, the incentive is to limit providers on the TIN-NPI list to reduce misalignment. CMS can make simple changes so that an ACO can include all providers but be assured that only patients receiving primary care are including in alignment.

One change is for CMS to allow for designation of "alignment provider" within the TIN-NPI submission so that cardiologists and other IM subspecialists will only have patients aligned if those specialists truly serve as primary care providers *as determined by the ACO*. (Thus specialists can be included without concern that their specialty care patients who receive primary care from another system are aligned to the ACO.) This would expand the TIN-NPI list and allow for broader application of waivers to increase provider engagement. This will also help reduce beneficiary turnover, as patients who are not tightly aligned to an ACO (aligned to Internal Medicine subspecialists) will not become part of the annual cohort.

Removing SNF E&M codes from alignment would also increase stability in alignment. Patients in nursing facilities for short-term care are generally cared for by physicians who are not their primary care provider. Patients are aligned to them because of the frequency of visits during this intensive stay, even though these physicians are not providing primary care. For the same reason that hospital E&M codes are not included in alignment, not including SNF E&M codes would allow systems to include providers who deliver care in SNFs without the risk that they would be aligned non-ACO patients.

Another simple refinement to the alignment methodology would be to process geographic utilization of services prior to alignment, rather than as part of the year-end exclusion process. If a patient historically receives more than 30% of their care outside of an ACO's service area, do not align them to the ACO (particularly important for the delivery systems with "snow bird" populations).

We recommend that CMS allow patients to "opt in" to the ACO (including those aging into Medicare), allowing the aligned population to better reflect the delivery system's primary care population – and would favor a patient's choice over a math formula. This was always intended to be a feature of the model, but has not yet been implemented.

We also recommend that CMS allow patients who transfer their care during the year (e.g. follow a PCP who moved to another ACO) to be de-aligned, or removed from the risk pool, even if that transfer is within the service area. Again, this would result in an aligned population that is more reflective of the system's true primary care population, and reflects patients' choices.

We recognize that following these recommendations would require a data system that is more flexible, to be able to accommodate alignment changes.

4. Improvements to the Claims and Reporting processes.

   We suggest that CMS work directly with a set of Pioneers and payers to develop improvements to the claims files formats/delivery process. Experienced delivery systems are more likely to apply if they have confidence in the claims files content and process, and they look more like formats and processes that exist with other payers. Areas for improvement include consistency of file formats, but even more importantly, processes for incorporating improvements/changes when revisions are needed.

   There are many areas where Pioneers experienced in population management and accountable care can be more of a resource to CMS. We recommend that CMS take more advantage of this, up to and including contracting with Pioneers as consultants and advisors, which could save CMS significant time, resources and rework.

   We recommend CMS develop a test environment to model any changes to claims files formats (eg ICD-10), with test files sent to Pioneers with 3 months' notice. In addition, CMS should benchmark with other payers (eg BCBS) how to best report performance/settlement to full-risk partners.

5. Consideration of new waivers.

   Just as CMS has approved a waiver of the three-day hospital stay to access the SNF benefit, we recommend considering waivers to allow more expansive use of home health services. We have been working closely with our Home Health partners in implementing our ACO initiatives, and have seen the benefits of the greater connection and communication to support high risk patients at home. We believe the ACO model could allow for judicious access to home health their services for patients who do not meet certification criteria, but would benefit from the intensive support; for continue limited services to support self-management after a certified episode, or even access short-term services that do not require a full episode but could be reimbursed by the visit. Such waivers would be especially attractive to organizations which have integrated home health services into their system of care.

B. Population-Based Payments: Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO

revenues would be coupled with a 40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

   FFS payment reductions could be used to engage providers outside the ACO in meeting triple aim goals. We could imagine creating a pool for performance-based payments – where facilities who perform highly on triple aim goals could earn additional dollars. However, we would need flexibility to set payments arrangements differently for provider type, and perhaps even down to the individual provider level.

   The ability to set create differential payment arrangements would make the PBP feature more attractive, and we would be more likely to participate. We imagine this would also be true for systems that are used to negotiating payment with outside providers.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

   CMS should allow ACOs to negotiate payment arrangements with any provider/supplier.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

   We strongly recommend that CMS move to a true global payment, budgeted capitation model. The PBP model currently available in the Pioneer model is not global payment, but rather a cash flow model. That said, CMS should let ACOs decide if they want to enter into PBPs, regardless of prior year's performance.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

   The kinds of tradeoffs that are referenced above could be avoided if CMS was to move to a full risk, agreed upon capitation payment rather than the overly complex BBR/PBP model. With a budgeted capitation amount, an ACOs would better know its monthly budget (in the current ACO

model, ACOs do not know their budget or benchmark until 6 months after the close of a calendar year). This would significantly reduce risk and volatility, and allow ACOs "room" for more progressive and creative ways to engage ACO provider/supplier to meet triple aim goals.

Section II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:

- **Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;**
- **Give providers more tools and resources to improve care outcomes and efficiency; and**
- **Continue to preserve beneficiary freedom of choice in FFS Medicare.**

CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

A. Transition to greater insurance risk –ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues.

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

   Full, global, budgeted capitation will encourage more experienced delivery systems to participate in the ACO model. Under full risk, there are opportunities for setting an appropriate budget using regional cost trends and care coordination investments, as an alternative to the baseline/benchmark method, again increasing transparency. A transparent, known, replicable budget will decrease volatility, a major barrier to engagement for experienced ACOs and their participating provider.

   Increasing transparency would also benefit the Medicare program in terms of encouraging research and modeling that could lead to even more effective programs. It would also give beneficiaries confidence in the program, knowing it can be validated/researched by outside entities. And

increasing delivery system participation in the ACO model means more beneficiaries would benefit from the coordinated care that is the hallmark of ACOs.

While monthly capitation is the payment mechanism most associated with and consistent with global risk-based payment, a shared savings model is not an obstacle to accountability for a full risk. A shared savings model could be used as settlement against a set monthly budgeted cap. There are really two components: one is the way the monthly budget is set (global monthly budget) and the second is cash flow or settlement against that budget (monthly cap or shared savings settlement).

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

An ACO's goal is to deliver the most effective care, regardless of site or provider. We recommend one risk pool that includes Medicare A, B &D. Much of the savings under global payment come from substituting high cost Part A services with lower cost Part B or Part D services. (For this reason, the current "alternative" risk options which separate Parts A&B are counterintuitive for groups that perform well under global payment.)

ACOs that have dual eligible patients in their aligned population may also want to be accountable for Medicaid payment/claims. It would depend on the ACOs experience with delivering services under the Medicaid benefit (see comments below).

3. Are there services that should be carved out of ACO capitation? Why?

We believe that service carve outs are antithetical to the ACO model. For example, our experience is that when HMOs moved to carving out Behavioral Health services, it led to disintegration of care for some of our most vulnerable patients. However, to be fully accountable for any service, an ACO needs a full claims data set. Currently, we are accountable for Behavioral Health with an extremely limited data set, and we recommend that CMS review its policy for withholding such a broad set of claims data – we believe it is overly broad.

We do recommend carve out of specific populations from the alignment methodology: patients who receive more than 30% of their care outside of an ACO's service area; and patients who transfer their care during the year (e.g. follow a PCP who moved to another ACO).

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

The ACO would want the ability to negotiate agreements with an individual provider (eg hospital or SNF). One example might be a payment arrangement that includes performance-based measures. It would be most administratively simple to allow the ACO to negotiate and administer these agreements.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be

adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk?

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

   ACOs can be risk bearing entities without taking on "full insurance risk" (depending on definition). For example, Massachusetts is in the process of issuing regulation on what they call "Risk Bearing Provider Organizations" (RBPO). While we will be certified as an RBPO that can take on the level of risk for which we contract, we still work with the payer, who has what we would refer to as ultimate "insurance risk."

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

   Not every ACO would be looking to become a Medicare Advantage Organization. Our infrastructure investments are in care delivery, and we would not be looking to take on health plan functions (eg claims payment, marketing, enrollment, member services). Also, it would not make sense financially for us to do so for Pioneer volume alone because it would cost us more per claim that it costs Medicare, which would actually add costs. It is important to have a model that does not require an ACO to be a health plan or invest in health plan functions. When we have dollars for investments, we want to always invest them in improving the care model.

   If it was necessary, an ACO like ours could contract with a health plan or third party administrator for health plan functions. However, we would have the same concern around adding costs since based on volume this would likely cost more than it costs Medicare.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

   The use of a national trend to set the benchmark creates, out of the gate, advantaged and disadvantaged ACOs. While we understand and support the desire, on a policy level, of reducing variation across markets, the use of a national benchmark is a very blunt instrument that will discourage low cost providers in high cost markets from participating, and vice versa.

   Use of a local or regional trend could more appropriately budget and reward providers, but even more importantly, would incorporate differences in regional cost levels into the trend methodology.

We would therefore suggest CMS consider a blended approach in calculating the annual trend factor that is applied to an ACO's budget. With the national growth trend accounting for 50% and the local growth trend the other 50%.

Lastly, the methodology should also include in the benchmark an ACO's investment in care coordination, particularly as those investments increase and billable events decrease.

Each of these recommendations could be incorporated into developing a global, budgeted capitation

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

Health status or HCC model risk adjustment is a key component of all of our global payment arrangements, with Pioneer as the only exception. While it is an imperfect model, health risk adjustment has the overriding benefits of being standard practice and a known and acceptable approach, and does not introduce the kinds of complexities and unusual features we see in the Pioneer methodology (in particular the decedent adjustments). Where an ACO is looking to take on significant risk, using a consistent approach reduces the risk of unknowns. Health status adjustment also allows for comparison across ACOs independent of variance in local costs. A historical cost model, on the other hand, builds those unit cost differences right into the budget.

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

We strongly recommend rewarding beneficiaries for more actively participating in the ACO model. Encouraging in-network care -- as defined by the individual ACO -- through eliminating or lowering copays or other benefit designs (small increase in Medicare costs) will decrease the costs of uncoordinated, out of network care (large decrease in Medicare costs), and deliver in-network care which is likely to be safer, and more connected to all the other high-value services the ACO provides (e.g. care navigation, disease management).

We also recommend that CMS reward beneficiaries, through cost sharing reductions, for selecting a PCP – because of the benefits of care coordination and also so that over time, alignment reflects a patient's actual choice. Again, a small cost investment that yields large savings.

Other opportunities for reducing or eliminating beneficiary cost sharing are: no copay for select medications, procedures or service that manage chronic disease; no copay for vaccinations. In addition to reducing financial barriers, we recommend that there be targeted positive incentives for following guidelines – eg no copays for six months if you are meeting goals, covered cost of smoking cessation program.

Another benefit could be transportation to medical appointments. Today, it is very unclear what is allowed for Medicare beneficiaries. Giving ACOs the authority to provide or cover the cost of appropriate transportation to medical appointments would be a tremendous benefit to both the patient and the ACO.

Lastly we recommend that ACOs with pharmacies have the option of developing a "branded" Medicare supplement/Medigap plan with part D. We believe that an ACO branded Medigap plan could help us meet the ACO's triple aim goals by offering benefit designs that not only ensure good stewardship of the Medicare dollar, but also provide opportunities for patient engagement in the ACO by encouraging, for example, use of an ACO's providers. Offering a Medigap plan will also be helpful in markets with high Medicare Advantage penetration, where patients enjoy the ease of getting all their Medicare benefits in a coordinated fashion.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

We recommend that CMS adopt strategies that encourage beneficiaries to "choose" the ACO model and chose their ACO – this is more forward looking (where I want to get my care today and going forward), than backward looking (where I got my care for the last three years) and honors patient choice. We recommend that CMS allow patients to "opt in" to the ACO so that the aligned population better reflects the ACO's primary care population – and again honors a patient's choice over a math formula. This was always intended to be a feature of the model, but was not implemented.

We also recommend that CMS allow patients who transfer their care during the year (e.g. follow a PCP who moved to another ACO) to be de-aligned, or removed from the risk pool, even if that

transfer is within the service area. Again, this would result in an aligned population that is more reflective of the system's true primary care population, and honors patients' choices.

B. Integrating accountability for Medicare Part D Expenditures– An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

   Because of the large number of Part D providers each of which has only a small percent (no one with more than 10%) of our aligned population in their plan, it did not make sense for us to pursue a business relationship with any one Part D plan, and it would unwieldy – significant work for small reward -- to pursue a relationship with many. We did have exploratory conversations with one Part D provider, but our interests were not aligned; the Part D provider was looking for opportunities to increase their own prescription sales, which would conflict with our goals of maximizing in-network utilization and care coordination through keeping part D prescriptions within our own pharmacies and in our medical record.

   We recommend that ACO with pharmacies have the option of developing a "branded" private Part D plan, and offer benefit designs that would not only insure good stewardship of the part D dollars, but also provide opportunities for patient engagement in the ACO by encouraging, for example, use of an ACO's pharmacies.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

   ACOs should be able to be accountable for Part D without having to be a Part D sponsor itself – that would be our preference.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

C. Integrating accountability for Medicaid Care Outcomes – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

   ACOs which have dual-eligible patients in their aligned population – particularly those who do not have global payment options for duals in their state – should have the option of taking full accountability for Medicaid costs and outcomes. This would provide incentives to build more coordination of care for Medicaid benefits (eg social and home supports) within the ACO, better serving these vulnerable patients. This should be an option – not a requirement – because many ACOs do not have experience/expertise being accountable for Medicaid benefits.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

   ACOs should be able to choose the subset of dual-eligibles for which they will take accountability. For example, ACOs that have developed a strongly geriatric model of care may not have the right model of care for younger, disabled patients.

   ACOs should not be required to take accountability for patients who have not been cared for by the ACO, unless the patient is opting in to the ACO and choosing a PCP.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare

FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

   CMS should work with the states to offer a unified global budget that combined Medicare and Medicaid expenditures.

D. Other Approaches for Increasing Accountability – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

   We are a healthcare delivery organization with 10% market share across a very large geography that includes many completing health systems and provider groups, so this would not work for us or in our market.

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

We recommend that the ACO retain full financial risk, and recommend against a "layered" ACOs where incentives may not be aligned. Care under a "layered" model is more likely to be uncoordinated, and patients more likely to be confused, by different entities which are independently accountable for the patient.

E. Multi-Payer ACOs – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

   If CMS adopts a more transparent global budget model and process, ACOs may be more comfortable spreading such a model with other payers, and those payers will be able to replicate the model and analyze the Medicare experience. This would speed adoption in the private market, as would refinements to the attribution model to make it one that other payers could easily adopt.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

   CMS is a standard bearer and pace setter. This positional leverage is most effective if CMS can promote stability and continuous improvement in the quality reporting program, increasing its institutional capacity for establishing:

   - Agreement around metrics that are widely recognized as clinically relevant. One example: hgb1ac control in diabetics is measured in *two ways* in the ACO measure set, and hgba1c < 8 is not recommended by the ADA geriatric committee due to being overly tight control clinically for frail elders. The choice of this measure seems both redundant and clinically unwise.

   - Metrics that are standard measures with broad use. One example: using the more common HEDIS specification for Med Rec rather than the unusual ACO Med Rec measure which has been a source of misinterpretation, reinterpretation and reporting error.

   - Consistency of interpretation via transparent audits trails across all provider data that is used to build empiric benchmarks. One example: non-audited data with low case numbers are given the same weight as audited data sampled from huge populations.

- Robust discussion around more advanced statistical approaches for ascertaining what is best practice as well as benchmark setting (e.g. use of the beta binomial or Hochberg method rather than un-weighted raw percentile builds).

If CMS can make noticeable improvements to the quality measurement program, this will establish CMS as a leader and the ACO quality measurement program as a standard, encouraging broader adoption of the ACO measures

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE & MEDICAID INNOVATION

Center for Medicare and Medicaid Innovation
Request for Information: Evolution of ACO Initiatives at CMS

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for Information (RFI)

SUMMARY

The Centers for Medicare & Medicaid Services (CMS) are seeking input on the following areas related to the evolution of Accountable Care Organization (ACO) initiatives.

1. A second round of applications for the current Pioneer ACO Model
2. New ACO models that encourage greater care integration and financial accountability

DATES: *Comment Date:* To be assured consideration, comments must be received by March 1, 2014.

ADDRESSES: Comments should be submitted electronically through the CMS Innovation Center's web page at: http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/

FOR FURTHER INFORMATION CONTACT: PioneerACO@cms.hhs.gov with "RFI" in the subject line.

BACKGROUND

Section 1115A of the Social Security Act, as enacted by section 3021 of the Affordable Care Act, authorizes the Center for Medicare and Medicaid Innovation (hereafter, the Innovation Center) to test innovative models of payment and service delivery that have the potential to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid and CHIP beneficiaries.

The Innovation Center's Pioneer ACO Model was designed to complement the Shared Savings Program, established under Section 3022, by offering participating ACOs a distinct set of payment arrangements and different methodologies for performing beneficiary alignment and expenditure calculations. The Pioneer ACO Model was also designed as a testing ground, where certain design elements could be developed and tested before being considered for incorporation into either the Shared Savings Program or another CMS program.

CMS is issuing this Request for Information (RFI) to obtain input on policy considerations for the next generation of CMS ACO initiatives. Topics of particular interest include (1) approaches for increasing

participation in the current Pioneer ACO Model through a second round of applications, and/or (2) suggestions for new ACO models that encourage greater care integration and financial accountability.

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes based contracting. The Model is now entering its third performance year with 23 organizations. In addition to increasingly aggressive risk arrangements, CMS offers eligible Pioneer ACOs the opportunity to transition from fee-for-service payments to monthly population-based payments to give these organizations more revenue flexibility in determining how to best motivate providers to improve quality of care and reduce costs for their patient populations. As more and more health care organizations begin to hone their skills in care coordination and engage in outcomes-based contracting, CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?
   A: Yes, BHN recognizes healthcare organizations have matured and are more willing to accept the risk inherent in value-based arrangements.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?
   A: BHN recommends limiting the number of selected organizations to those with the highest potential for success. We respectfully offer that CMS may not currently have the operational capacity to effectively administer a Pioneer ACO model for all organizations that meet the qualifying criteria.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?
   XXX

B. **Population-Based Payments:** CMS allows Pioneer ACOs to transition to population -based

payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a 40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

   XXX

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

   XXX

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead

establish clear requirements for financial reserves? Why or why not?

A: Yes, with the level of beneficiary turnover year-over-year in the Pioneer program six months or more are required to see shared savings as a result of ACO programs. Due to this flaw in the model, and the methodology used to determine ACO PBP eligibility, many ACOs may not have an opportunity to pursue PBP with providers/suppliers. Yet, it is an important incentive that will help ACOs achieve the Triple Aim.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

XXX

Section II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:

- Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;
- Give providers more tools and resources to improve care outcomes and efficiency; and
- Continue to preserve beneficiary freedom of choice in FFS Medicare.

CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

A. **Transition to greater insurance risk** –ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues.

    1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage

organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

A: BHN recommends that CMS implement a prospective payment, with an incentive closer to 100 percent risk for Parts A, B and D. There should be a primary care incentive payment upfront to entice PCPs (like CPCI) and MSR should be eliminated.

In addition:

- BHN would suggest that CMMI leverage the existing Pioneer program and MA program infrastructures to administer this new model, particularly as it relates to claims administration, compliance program management and quality performance management.
- CMMI should consider insulating participating physicians from dramatic changes like SGR adjustments and sequestration cuts to improve physician engagement. We are concerned about primary care physician groups' interest in participation as a result of multiple reductions and current and future sequestrations on beneficiaries for inpatient spend. Additionally, consider providing safe harbor for participating physicians related to regulations like Stark and Anti-Trust.
- BHN recommends CMMI channel all provider claims submissions for attributed ACO beneficiaries through a designated MAC. In this way logic can be applied to redirect ACO beneficiary claims to Pioneer ACOs and provide the ability to access claims data sooner. The process may vary slightly depending upon claims payment processors.
- Finally, ACOs should have zero downside risk resulting from poor medical cost or quality performance for patients in their first year of eligibility. This should adequately shield ACOs from population churn and from unique events resulting from medical tourism or catastrophic event. This also provides the ACO with adequate time to engage new beneficiaries in the organization's case management, prevention and educational programs.

While these changes are significant, they are reflective of the fact that ACOs make a substantial investment in the first year onboarding of Pioneer beneficiaries. Realizing a year-over-year turnover in the 30 – 40 percent range represents a dramatic loss in

investment for Pioneer organizations.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

   A: Medicare Parts A, B, and D

3. Are there services that should be carved out of ACO capitation? Why?

   XXX

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

   XXX

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk?

   A: BHN believes a Medicare Advantage benefit design concept would be a great improvement to the Pioneer ACO program. We could improve in-network utilization which will reduce costs and variation, while improving quality of care. In addition, we anticipate the opportunity to build in more activities to improve member engagement.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

   XXX

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

   A: BHN believes organizations with experience running MA plans have the ability to apply existing infrastructure investments into the ACO model. BHN advocates strongly for CMS to consider leveraging ACO's who have investments in MA infrastructure and develop models that reflect MA benefits.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

   XXX

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

   XXX

10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

    A:. Full insurance risk for Pioneer members cannot succeed unless there are benefit design elements that protect the ACO. We have several important recommendations in this area. Highlights of the recommendations include:

    - **Choose Quality:**
      Enhance beneficiary choice by identifying the highest quality physicians in their community, and reward beneficiaries for encounters with those physicians by offering reduced copays/coinsurance.
    - **Choose Value:**
      BHN recommends CMMI exercise its authority, noted under Section 3021 of the PPACA, to approve a waiver that allows the Medicare benefit to be enhanced to reward beneficiaries for making value-based healthcare choices. The benefit enhancement should be standardized and consistent across all Pioneer ACOs. Additionally, BHN recommends that CMMI incentivize beneficiaries to stay in-network through lower or waived copays/deductibles or lower premiums.
    - **Responsibility for Costs of Enhanced Benefit:**
      BHN recommends that Pioneer ACOs could absorb the cost of the added benefit, financing that amount through their cost savings. Pioneer ACOs will choose to expand their preferred networks, thereby increasing their benefit/cost burden, but only to the extent that they project enough cost savings to offset the benefit

subsidization. We strongly urge CMMI, that if shared savings designs are used for the next iteration, they provide shared savings quarterly with a reasonable but small percentage withheld for eventual settlement.

- **Leverage Existing Infrastructure:**
  BHN recommends that CMMI leverage the existing Pioneer model and MA program infrastructure to facilitate claims payments to providers, and to perform patient access testing. CMS should recognize and reward high performing ACOs. This will limit the noise and disruption in the health care market as new ACOs form and begin to create confusion among consumers. Finally, require beneficiaries to choose ACOs certified by URAC or another accrediting organization.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?
    XXX
12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?
    A: BHN recommends network adequacy tests, similar to Medicare Advantage programs, as a precautionary measure to protect beneficiaries.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?
    A: BHN recommends that CMMI allow beneficiaries to become voluntarily attributed to a Pioneer ACO. If traditional Medicare beneficiaries complete a standard application and data opt-in form, choose a participating primary care physician, and submit the required paperwork to CMS during the Annual Attribution Period, they should be allowed to

participate in the benefits of the Pioneer ACO model. As awareness has increased around the Pioneer model and Accountable Care, we have seen more community interest in "joining" our ACO.

In addition, related to direct communication with beneficiaries, BHN recommends the following opportunities:

- BHN recommends that we are not limited by communication black-out periods. Also, while template communication can be helpful, allow us to craft our own message when it is more applicable to our local audience.
- BHN recommends CMMI allows ACOs to look at CAHPS survey patient-level detail. This would allow ACOs to do additional analysis, learn from the results and take needed action.
- Expand the opportunity to educate beneficiaries on the benefits of in-network services.
- Approve a larger (greater than $50) incentive allowance for the engagement of beneficiaries to create loyalty. This might include a point system or punch card that can be exchanged for retail gift cards or health-related products.
- CMMI should consider the beneficiaries' reading levels in all materials that ACOs are required to send.
- BHN recommends CMS provide caretaker (emergency contact) information in beneficiary demographic data. Give ACOs the opportunity to communicate with caretakers.
- Allow ACOs to edit the model ACO ID cards to include beneficiary name, year and other relevant information.
- Finally, CMMI should improve marketing/communication review time to a maximum of two weeks to allow more timely communication with beneficiaries.

B. **Integrating accountability for Medicare Part D Expenditures**– An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the

promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

XXX

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

   XXX

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

   A: No, we don't currently have the needed data. BHN recommends that CMS mandate Part D expenditure data to be sent to CMS, or for ACOs to be included in the monthly claims files.

C. **Integrating accountability for Medicaid Care Outcomes** – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

   XXX

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

   XXX

3. What should the role of States be in providing appropriate incentives to foster the

development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

XXX

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

   XXX

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

   XXX

D. **Other Approaches for Increasing Accountability** – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

   XXX

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments.

If so, what would the most critical features of such a "layered" ACO be and why?

XXX

E. **Multi-Payer ACOs** – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

   XXX

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

   A: BHN recommends CMMI create synergies with industry standard quality measures. For example:

   - Utilize MA quality measures to create synergies between STARS and ACO 33 quality measures. Quality measures should focus on prevention and wellness as opposed to screening measures.
   - Design measures around evidence-based USPSTF recommendations, instead of recommendations by smaller specialty society organizations to reduce over diagnosis of chronic conditions. Harmonize clinical measures with HEDIS/NQF measures used in Medicare populations.
   - Narrow the focus to a manageable number of measures allowing for education and meaningful change--10 clinical measures are easier to influence than 33. Shift to outcome-based measures rather than process-based measures.
   - Reduce reliance on chart abstraction and focus on CPTII Coding for outcome measurement.
   - Submit ACO clinical measure samples quarterly rather than annually. Provide benchmark targets before the Performance Year begins, allowing ACOs to better gauge their performance against those targets and make adjustments as needed.

Baxter

February 28, 2014

Patrick Conway, M.D.
Deputy Administrator for Innovation and Quality and CMS Chief Medical Officer
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, MD 21244

RE: Request for Information (RFI): Evolution of ACO Initiatives at CMS

Dear Dr. Conway:

Thank you for this opportunity to provide our input in response to the Centers for Medicare & Medicaid Services (CMS) Request for Information on Accountable Care (ACO) initiatives at CMS and specifically, a second round of applications for the current Pioneer ACO Model and new ACO models that encourage greater care integration and financial accountability. Baxter commends the Agency for seeking public input to inform the Agency's evaluation of ways in which to expand its ACO initiatives.

For more than 85 years, Baxter has assisted healthcare professionals and their patients with the treatment of complex medical conditions, including hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma, and other conditions. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives.

In the RFI, the Agency describes a potential transition to greater insurance risk for ACOs.[1] The Agency acknowledges that ACOs assuming full insurance risk would face similar issues to current organizations in the Medicare Advantage program, at the same time, they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. In that context, the Agency asks whether there are services that should be carved out of ACO capitation. Baxter urges CMS to consider carving out hemophilia factor products from any potential ACO capitation and calculation of Medicare shared savings amounts.

Hemophilia factor products are very unique products, used to treat bleeding disorders such as Hemophilia A, Hemophilia B, and Acquired Hemophilia among other rare disorders. For those patients who require these therapies, these products are life-saving and sustaining and thus extremely important. Patients with severe hemophilia, for example, produce less than 1 percent of the normal amount of the affected clotting factor and are dependent on factor from infusions to treat or prevent bleeding episodes.

While concentrated on a small population of beneficiaries, these products are relatively expensive. As a result, Baxter is deeply concerned about the impact that including these products could have on beneficiaries and their access to these critical therapies. Applying the

[1] CMS, Evolution of ACO Initiatives at CMS, RFI, Section II., paragraph A.

cost of hemophilia factor products to an ACO could skew the shared savings calculation and dangerously create perverse incentives for physicians to stint on care and undersupply these therapies to beneficiaries in order to gain personal financial reward. For the safety and care of Medicare beneficiaries with hemophilia, Baxter urges CMS to carve out hemophilia factor products from any ACO capitation.

Carving hemophilia factor products from a Medicare payment bundle for these reasons is not new. Recognizing the unique nature of blood clotting factor in 1989, Congress included in Omnibus Budget Reconciliation Act (Pub. L. 101-239) a carve out from the hospital inpatient payment for "costs with respect to administering blood clotting factors to individuals with hemophilia." In the Balanced Budget Act of 1995, Congress again confirmed the need for separate payment for blood clotting factors, and permanently extended the additional payments for costs of administering blood clotting factor to Medicare beneficiaries with hemophilia. This language is contained in Section 1886(a)(4) of the Social Security Act.

Again, thank you for the opportunity to provide our input on the development of ACO initiatives under the Agency. We strongly believe that for the safety and care of Medicare beneficiaries with hemophilia that CMS should exempt hemophilia factors products from ACO capitation and the calculation of Medicare shared savings. If you have any questions or if we can be of any assistance, please do not hesitate to contact me at 202.281.8524 (mark_coin@baxter.com).

Respectfully,

Mark Coin
Director, Public Policy and Reimbursement

Center for Medicare and Medicaid Innovation
Request for Information: Evolution of ACO Initiatives at CMS

Organization Name: Bellin-ThedaCare Healthcare Partners
Contact: David Krueger, MD
Phone: 920-380-4956
Email: david.krueger@thedacare.org
Part of both a Medicare ACO and a Commercial ACO

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for Information (RFI)

SUMMARY

The Centers for Medicare & Medicaid Services (CMS) are seeking input on the following areas related to the evolution of Accountable Care Organization (ACO) initiatives.

1. A second round of applications for the current Pioneer ACO Model
2. New ACO models that encourage greater care integration and financial accountability

DATES: *Comment Date:* To be assured consideration, comments must be received by March 1, 2014.

ADDRESSES: Comments should be submitted electronically through the CMS Innovation Center's web page at: http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/

FOR FURTHER INFORMATION CONTACT: PioneerACO@cms.hhs.gov with "RFI" in the subject line.

BACKGROUND

Section 1115A of the Social Security Act, as enacted by section 3021 of the Affordable Care Act, authorizes the Center for Medicare and Medicaid Innovation (hereafter, the Innovation Center) to test innovative models of payment and service delivery that have the potential to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid and CHIP beneficiaries.

The Innovation Center's Pioneer ACO Model was designed to complement the Shared Savings Program,

established under Section 3022, by offering participating ACOs a distinct set of payment arrangements and different methodologies for performing beneficiary alignment and expenditure calculations. The Pioneer ACO Model was also designed as a testing ground, where certain design elements could be developed and tested before being considered for incorporation into either the Shared Savings Program or another CMS program.

CMS is issuing this Request for Information (RFI) to obtain input on policy considerations for the next generation of CMS ACO initiatives. Topics of particular interest include (1) approaches for increasing participation in the current Pioneer ACO Model through a second round of applications, and/or (2) suggestions for new ACO models that encourage greater care integration and financial accountability.

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes based contracting. The Model is now entering its third performance year with 23 organizations. In addition to increasingly aggressive risk arrangements, CMS offers eligible Pioneer ACOs the opportunity to transition from fee-for-service payments to monthly population-based payments to give these organizations more revenue flexibility in determining how to best motivate providers to improve quality of care and reduce costs for their patient populations. As more and more health care organizations begin to hone their skills in care coordination and engage in outcomes-based contracting, CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

   It is not clear to us why CMS would have interest in expanding the program when there is already the option to participate in MSSP. The Pioneers are narrowing to a core group that has developed some experience working together. Additions to the cohort may be disruptive at this point in time. It would be better to wait for the transition point after year 5 to introduce a change in the cohort.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

   If additional applicants are solicited, CMS should limit the number of selected organizations in order to maintain the collaborative trust that the existing organizations have developed over the past few years. If new groups are allowed to join, it should be timed to coincide with a rebase year, specifically entering in year four or entering beyond year five. Joining in other years would not allow an apples to apples comparison amongst the groups if the financial calculations are anchored to different base years.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

   We have suggestions for refinements but none that would be geared toward increasing applicants.

B. **Population-Based Payments:** CMS allows Pioneer ACOs to transition to population -based payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

   Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a 40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

   1. Would being able to choose different FFS reduction amounts for Part A and Part B

services be of significant import when deciding to participate in the PBP? Why or why not?

Choosing different FFS reduction amounts for Part A and Part B is not important to our decision. Since PBPs are still reconciled to the fee schedule, cash flow timing is the only thing that changes. This does not address the underlying structural problem of fee for service payments. We would need to move to a more capitated model in order for PBPs to make sense for our organization.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

   No comment.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

   Since this is only a cash flow issue, we do not see a reason to require a certain level of performance in order to participate. Establishing clear requirements for financial reserves should be enough.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

   No comment.

Section II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:

- Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;
- Give providers more tools and resources to improve care outcomes and efficiency; and

- Continue to preserve beneficiary freedom of choice in FFS Medicare.

CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

A. **Transition to greater insurance risk** –ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues.

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

   Yes, CMS should offer capitation with insurance risk. Capitation will spur the innovation necessary to transform health care delivery. Benefits would include greater predictability for the Medicare Trust and the creation of an environment that will accelerate improvements in care. Capitation would remove the incentive to overproduce. The potential risk is incenting the reduction of care. However, this risk can be mitigated by quality requirements and greater transparency of results. There also remains the risk of overbearing administrative requirements that need to be restrained. If beneficiaries will be allowed free choice, the insurance risk would need to be reduced compared to Medicare Advantage (MA). If the insurance risk is similar to MA then we need the same ability to direct patients to providers that are high quality and low cost. If CMS does not allow ACOs some ability, similar to that of MA, to manage risk, there may not be wide acceptance of ACO capitation.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

   As previously stated, we do not want FULL insurance risk for this population. There needs to be limitations for catastrophic claims as well as limitations on the total amount of financial risk exposure including Part D especially as it relates to high cost drugs. However, ACOs that hold partial insurance risk should still hold some accountability for all payment areas including Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries.

3. Are there services that should be carved out of ACO capitation? Why?

   High dollar services such as catastrophic events, cancer treatment, high cost drugs, and death should be carved out of capitation and upside only shared savings methodologies should be applied. This would encourage performance in the high cost population segment but also mitigate risk to the provider. An ACO is not an insurance company and does not have a sufficient population over which to spread the risk of catastrophic losses. Devising the system in this way would essentially spread the catastrophic risk across the country. Alternatively, CMS could retain the risk associated with catastrophic losses and carve it out in setting the ACO total cost of care (i.e. capitation) risk budgets. Consistent with reinsurance practices in commercial insurance we would recommend establishing a dollar stop loss threshold over which the ACO is exempt from financial loss. This same threshold could also be used to define a limited upside only segment of the population.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

   The answer is somewhat dependent upon the comprehensiveness of the ACO. Assuming the ACO is able to put together a comprehensive panel of providers this need may be minimal. However, it is likely the ACO will have a need to contract with a "wrap network" to provide services should a participant seek services outside the immediate service area. The ACO will also likely need to contract with a tertiary and transplant network for very specialized care.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk?

   The following Medicare Advantage elements would benefit the ACO:

   - Allowing the ACO to operate under HMO and PPO benefit designs would provide the ACO enhanced ability to manage the risk.
   - Requiring beneficiaries to disenroll should they have an extended absence (i.e. six months) from the service area would prevent the ACO from accepting risk

for non-ACO providers.

- Allowing beneficiaries to actively enroll in Medicare Advantage provides more awareness to the beneficiary of the providers responsible for their care. Active enrollment of beneficiaries should be extended to ACOs.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

   Licensure requirements for ACOs are not well defined. ACOs would likely be required to have the same financial reserves that insurance companies have. But ACOs will only have partial insurance risk. Regulating an ACO would be difficult for the State Office of the Commissioner of Insurance to define but, given the limited risk, the financial reserve requirements should also be limited. ACOs would need waivers to existing fraud and abuse laws, anti-kickback, etc. These regulations and laws prevent ACOs from creating financial arrangements that would drive improvements and lower cost in health care.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

   The answer to this question is dependent upon whether or not the ACO will be administering the benefit plan. Should CMS continue to administer the benefit designs under the ACO it is likely the ACO would not need to provide many of the back office functions of a health plan. Assuming the above, the ACO will only need to add some medical management components to help control the risk. If CMS discontinues its benefit administration the ACO will have to replicate services commonly provided by health plans.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

CMS is a national insurance plan. As such, reimbursements should be similar across the country and should only vary by regional cost of living differences. Using trends does not take into account the total cost of care which is the more important metric. A disadvantage of using the national growth trends is that already low cost providers may be unable to match a lower trend compared to those that are high cost and that have more opportunity to remove waste. One advantage to using the national growth trend is that it rewards collaboration in a regional marketplace. Regional trend references will discourage this collaboration.

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

   Advantage to medical risk-adjustment is that it levels the playing field. The problem with risk-adjustment is that it is very difficult to accurately avoid creating the wrong incentives. A longer term disadvantage to risk-adjustment is that as the health of a population is improved, risk-adjustment will decrease reimbursements. If the risk adjustment process reduces reimbursement to ACOs who are successful in improving the health of their population and thus lowers the population's illness burden, these competing incentives will quickly become a dissatisfier for ACOs. We suggest setting a baseline using demographic adjustments combined with risk adjustment for disease burden. Then, after the baseline is set, use demographic adjustments only.

10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

    We strongly support benefit enhancements for beneficiaries receiving services by ACO providers. For the ACO to be successful their focus needs to be on cost, quality and improving the patient experience. Having a benefit design that supports this will help

both the providers and the beneficiaries. Reducing copayments, coinsurance and possible deductibles for ACO provided services would be a good first step.

Additionally, we would like to see a benefit design that supports reference pricing. If a beneficiary obtains their care from an ACO designated center of excellence the beneficiary's cost would be defined. Should they obtain their care from a non-designated center, the beneficiary would be responsible for the cost that is in excess of the reference price.

Wellness is a proven strategy to lower health care costs. However, wellness benefits are often provided outside of health plan benefits. We recommend wellness benefits be included in the traditional Medicare plan design. For example, ThedaCare has been successful with a program designed to educate patients on nutrition, healthy cooking, diet, exercise, stress management and the recognition of healthy and unhealthy behaviors. This has been an effective program which has greatly reduced the health risk of the enrolled patient population and provided improved health for people with certain chronic conditions.

The Annual Wellness Visit is an effective tool to obtain the patient's health profile and gain an understanding of their lifestyle and behavior as well as provide appropriate screens. We have learned that patient participation requires incentive. Accordingly, we recommend allowing the provider organization to provide enhanced benefits to patients that engage in their own health care.

We might consider expanding the concept to other aspects such as providing additional incentives if the beneficiary has an advanced directive or living will in place or attends an "Informed Decision" counseling session before proceeding with an elective surgery. The better we are able to honor patient choices, the better the care we will be able to provide.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

If there are incentives to reduce cost without appropriate incentives to improve care, there could be potential issues. Appropriate safeguards would include: transparency of

outcomes data and patient satisfaction with increases/payments tied to these metrics.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

    It is our recommendation that ACOs not be responsible for catastrophic risk and that this risk be reinsured through CMS. We would expect that the capitated rate would carve out this risk as it is more predictable for a large population compared to the smaller population being serviced through an ACO.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

    Yes, we believe a beneficiary should be allowed to elect alignment to an ACO even if they would not have been aligned to the ACO through claims-based attribution. Beneficiary selection of an ACO is a prospective real-time decision made by that beneficiary to actively choose a health care system for their health care. Given transparency of cost and quality, a beneficiary should be given the right to choose their provider which is consistent with one of CMS's goals to allow beneficiary choice. We believe patient engagement in their care is paramount and selecting their health care provider of choice should be their first decision.

    Claims-based attribution is a retrospective review of care patterns which may not be representative of where the beneficiary desires to obtain their care in the future. It is likely claims-based attribution came about as a proxy since many current insurance products and Medicare don't offer a beneficiary the option to select their preferred

provider.

B. **Integrating accountability for Medicare Part D Expenditures**– An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

   Barriers to the effectiveness of collaboration include the lack of transparency and full disclosure with respect to contractual relationships with pharmaceutical companies. Lack of transparency related to rebates and grants and the inability to modify the formulary has prohibited managed care companies from collaborating successfully with Pharmacy Benefit Managers (PBM) who are the Part D sponsors. If these barriers can be removed an ACO has a better chance of improving outcomes and coordinating care. If the barriers cannot be removed, they create a competing incentive between the Plan D sponsor and the ACO. CMS should allow the ACO to change/modify a formulary in an effort to avoid duplicate drugs with same ingredients and meet the needs of the population.

   Additionally, if the ACO were to consider a capitation agreement with the Part D Sponsor it lacks access to sufficient data upon which to determine the reasonableness of capitation target and thus would be disadvantaged in negotiations. We would suggest a transition period for part D risk and the ability to link to preferred part D vendors.

   CMS might allow at risk ACOs to collaborate to establish their own Pharmacy and Therapeutic (P&T) Committee to evaluate the most appropriate formulary which could then be used by all. Participating ACOs could also collaborate to use their purchasing power to influence favorable pharmaceutical agreements and jointly select a PBM to administer the benefit.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or

through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

Yes, ACOs would be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies. In managing the risk of a population, ACOs will want to mitigate competing incentives across all the modalities for care. Since pharmacy benefits are a key component of practically every beneficiary's care plan; we desire to avoid situations where the risk/financial responsibility of aspects of the care plan (i.e. pharmacy) get in the way of providing the most effective care. If the responsibility of Part D is held by a non-ACO participant, they may put in place barriers to care that mitigate their risk but negatively impact the total cost, quality and outcome of the care delivered.

We don't see the value of separately licensing ACOs under state law for accepting Part D risk, especially if such licensing is not necessary for Part A and B risk. It is quite likely that should an ACO accept Part D risk it will administer the risk/benefit through a state licensed PBM so we don't understand what appears to be a duplicate requirement.

We believe that Part D should be included in the expenditure target for the ACO. In managing the risk of a population, ACOs will want to mitigate competing incentives across all the modalities for care and be free to choose the care plan that is most effective in improving cost, quality and patient outcomes. Pharmacy is a key component of practically every beneficiaries care plan and thus we never want risk/financial responsibility to get in the way of providing the most effective care.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

   Access to pharmacy data has been limited thus we don't have enough data to evaluate the risk.

   ACOs will need access to multiple years of pharmacy claims for their attributed

population along with the associated member months that would allow them to evaluate utilization and initial risk. The ACO's attributed population profile by disease state, health condition, HCC index and utilization metrics (i.e. avg. no. of scripts per beneficiary, ingredient cost per day, etc.) could be compared to CMS normative benchmarks so as to gain a better understanding of the ACO population and identify opportunities.

C. **Integrating accountability for Medicaid Care Outcomes** – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

NO COMMENTS MADE IN THIS SECTION

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?
2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?
3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?
4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic

health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

D. **Other Approaches for Increasing Accountability** – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

   No Comment.

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

   Under a global capitation agreement, our organization would be interested in a model that incorporates per member per month primary care management fees within an ACO context and episode-based payments. The primary care management fee supports the additional work and infrastructure needed to manage a population. Episode-based payments engage specialists in improving clinical and operational

efficiencies and align them with the overall objectives of the ACO. Including episode-based payments in the ACO model whereby their cost applies toward the global capitation target provides a safeguard against over production of procedures that could occur in a stand-alone episode-based payment model. We believe these reimbursement models are complementary.

E. **Multi-Payer ACOs** – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

   CMS should encourage multi-payer collaborations through continuation of the State Innovation Models Initiative. Each state should be encouraged through this grant program to build a multi-stakeholder process which brings employers, payers, state governments, providers, and CMS to the same table. The commercial payers are more likely to participate in payment redesign if CMS is at the table. Within individual markets CMS should encourage commercial insurers to work with ACOs on more aggressive payment models. This would include experiments such as full risk capitation etc. CMS could incent commercial payers to work with ACOs by lending analytic support. CMS could also incent commercial payers by allowing access to the Medicare claims file for the population of fee-for-service Medicare beneficiaries that is served by the ACO.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

   There are two potential approaches, national and regional. At the national level, we would propose that CMS lead the development of a national quality platform that would have uniform metrics and specifications that have achieved multi-stakeholder approval. All entities should then be encouraged to adopt the

"national plan" as the gold standard reference for every quality program.

At the state level, CMS should delegate the reporting of quality measures to established publicly reporting entities in each state. Examples include Minnesota Community Measurement (MCM) and the Wisconsin Collaborative for Healthcare Quality (WCHQ). These organizations and many others throughout the country have already established a positive rapport with physician groups. These organizations are ready and willing to take on the work of managing CMS's quality measures and probably can improve on the process of collecting and reporting the measures. Each state through a multi-stakeholder initiative supported by the State Innovation Model Initiative grant should be able to develop their core set of measures used for quality reporting. This set of measures should be submitted to CMS for approval. The state should be required to have a reporting mechanism such as MCM or WCHQ which regularly reports to the ACO and to CMS on the results of the quality performance of each organization.

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE & MEDICAID INNOVATION

Center for Medicare and Medicaid Innovation
Request for Information: Evolution of ACO Initiatives at CMS

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Request for Information (RFI)

SUMMARY

The Centers for Medicare & Medicaid Services (CMS) are seeking input on the following areas related to the evolution of Accountable Care Organization (ACO) initiatives.

1. A second round of applications for the current Pioneer ACO Model
2. New ACO models that encourage greater care integration and financial accountability

DATES: *Comment Date:* To be assured consideration, comments must be received by March 1, 2014.

ADDRESSES: Comments should be submitted electronically through the CMS Innovation Center's web page at: http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/

FOR FURTHER INFORMATION CONTACT: PioneerACO@cms.hhs.gov with "RFI" in the subject line.

BACKGROUND

Section 1115A of the Social Security Act, as enacted by section 3021 of the Affordable Care Act, authorizes the Center for Medicare and Medicaid Innovation (hereafter, the Innovation Center) to test innovative models of payment and service delivery that have the potential to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid and CHIP beneficiaries.

The Innovation Center's Pioneer ACO Model was designed to complement the Shared Savings Program, established under Section 3022, by offering participating ACOs a distinct set of payment arrangements and different methodologies for performing beneficiary alignment and expenditure calculations. The Pioneer ACO Model was also designed as a testing ground, where certain design elements could be developed and tested before being considered for incorporation into either the Shared Savings Program or another CMS program.

CMS is issuing this Request for Information (RFI) to obtain input on policy considerations for the next generation of CMS ACO initiatives. Topics of particular interest include (1) approaches for increasing

participation in the current Pioneer ACO Model through a second round of applications, and/or (2) suggestions for new ACO models that encourage greater care integration and financial accountability.

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes based contracting. The Model is now entering its third performance year with 23 organizations. In addition to increasingly aggressive risk arrangements, CMS offers eligible Pioneer ACOs the opportunity to transition from fee-for-service payments to monthly population-based payments to give these organizations more revenue flexibility in determining how to best motivate providers to improve quality of care and reduce costs for their patient populations. As more and more health care organizations begin to hone their skills in care coordination and engage in outcomes-based contracting, CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not? CMS should consider additional organizations provided they have adequate IT structure, governance, and capital and subject to CMS' ability to support additional ACOs.
2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?
   CMS should limit the number of organizations to the number that they can support. CMS also needs to consider that as the number of ACO beneficiaries increases it may impact the ability to have a reasonably sized equivalent reference population available for comparison.
3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

   The refinements mentioned in Section B need to be made irrespective of whether CMS adds more applicants or not.

B. **Population-Based Payments:** CMS allows Pioneer ACOs to transition to population -based payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under

Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a

40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP? Why or why not? Yes, it is very important to be able to choose different FFS reductions for Part A and Part B because we need to make different financial arrangements between Part A and Part B providers. We also would like to be able to use different reduction amounts among Part A and Part B providers.
2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not? We would like the flexibility to extend PBP to any Medicare provider so that they have a stake in the program and its success.
3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?
   CMS should reconsider this requirement and separate the decision to implement a PBP from an ACO's ability to earn surpluses. There are many successful programs that are

well organized and provide cost-effective care under Medicare FFS and therefore may start out with lower budgets that could be disadvantageous. PBP is essentially a withhold; provider groups should be allowed to implement this type of reimbursement program outside of surplus generation. CMS also already includes a requirement for financial reserves.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

It would be beneficial to separate the TIN/NPI list of providers used for alignment from the TIN/NPI list used for fee reduction (PBP) as they serve different purposes. We want to have providers on the PBP list who are not on the alignment list.

Section II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:

- Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;
- Give providers more tools and resources to improve care outcomes and efficiency; and
- Continue to preserve beneficiary freedom of choice in FFS Medicare. CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

A. **Transition to greater insurance risk** –ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice.

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries? [Proprietary response.]

2. What categories of spending should ACOs at full insurance risk be responsible for? (For

example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

ACOS should have the option to choose what Medicare components they feel comfortable being at risk for and be able to phase in the risk over time.

2. Are there services that should be carved out of ACO capitation? Why?

If at risk for Part D, ACOs should be protected from extremely high-priced, necessary drugs such as those for hemophiliacs and new high cost technologies and drugs.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

We would adopt contracts where it might make sense to bring the entity into the ACO, for example in instances where it would create better clinical integration to take a fee reduction or negotiate a better rate. We need to be able to continue to only be responsible for Medicare payment rates if we cannot reach other agreements with non-ACO providers and for CMS to pay claims to non-ACO providers.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk?

   Provider ACOs should not be subject to all the marketing constraints that apply to MA plans. In addition, we would need complete data with no ability for beneficiaries to opt-out, or if beneficiaries opt-out of data sharing then they cannot stay aligned.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

   We believe that all current waivers should continue. In terms of state requirements, the challenge is getting state and federal government to agree to reasonable capital reserves requirements. We would need a wavier that allows a path for meeting state licensing requirements including state reserve capital requirements less onerous than those that currently exist (there is a precedent for this in Massachusetts). We would need federal financial support in the event of a catastrophic event, such as a major earthquake.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

   An ACO should be able to choose whether CMS pays claims or the ACO partially or fully takes on that responsibility. If an ACO takes this on they will need to have infrastructure to take on claims paying responsibilities.

   ACOs, particularly those paying claims, would need enrollment systems and customer service functions, as well as benefit determinations and adjudication structures.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead? Moving to full risk would

require a new financial model. To be fair, local reference expenditure trends should be used and full risk adjustment including patient functional ability (frailty scores) should be incorporated.

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.). We believe that we should have the risk adjustment categories available to MA plans that account for institutional patients, dual-eligible patients, age, and takes into account frailty.
10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid? CMS should cover cost of IV drugs at home and non-self-injectable drugs and reduce or eliminate copays in the Part B and Part D program so that these services can be delivered in a home setting without incentivizing patients to be admitted to receive better coverage under Part A benefits. CMS should provide benefit incentives to beneficiaries, so that there is differential cost sharing for providers in versus out of ACO. CMS should waive copays and deductibles to remove barriers to care and to encourage use of a preferred network focused on care coordination. Additionally the three-day SNF waiver is an important tool for delivering necessary care in a lower cost setting.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

No comment.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection? Protections afforded in the MA program seem adequate.
13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are

advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

Our patients should be able to elect to be aligned to the ACO at any time during the year. Additionally there is a lot of instability in alignment and CMS should consider asking beneficiaries who they see as their primary care physician.

B. **Integrating accountability for Medicare Part D Expenditures**– An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

   Having so many different Part D plans active in our market makes it difficult as so many relationships would need to be initiated and maintained. Additionally we would need to get from CMS the dollars associated with the drug claims as currently only get the drugs prescribed.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method? We would be interested in this but unable to comment on the advantages and disadvantages.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes? As an ACO, we should have the option to choose to accept risk for Part D only if we have complete drug data — we wouldn't take risk without complete cost data.

C. **Integrating accountability for Medicaid Care Outcomes** – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by

States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes? This should be an option for an ACO, but not a requirement.
2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO? CMS should preserve the option for ACOs to decide to take on accountability for any of these populations, but not require it. An ACO should only have accountability for beneficiaries that it has historically treated on a primary care basis or beneficiaries who elect into the ACO.
3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?
   States should provide infrastructure monies, reasonable payments for Medicaid beneficiaries cared for by the ACO, and education to beneficiaries and the public on the benefits of integrated care systems. All efforts should be made to ensure that the model coordinates Medicare and Medicaid benefits, which means including providers in the discussions on the design of the program structure.
4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?

As an ACO we have a data warehouse and analytics tools for the claims data that we receive. Missing opt-out data is a problem; we could not have aligned beneficiaries who opt-out in a full risk arrangement.

What are the capabilities of providers in integrating this data with electronic health records? Our ACO has been working on this for many years — it is a complex and costly endeavor.

What are the capabilities of integrating information for care received in the community or from other non-traditional care providers? We are working with our community providers to share information and incorporate key information into our EHR. The complexities and costs increase exponentially when the provider is not part of our network.

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures? CMS and States should offer a unified shared savings arrangement.

D. **Other Approaches for Increasing Accountability** – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

   A provider-led community ACO will work best when it does not have extensive overlap with other provider ACOs. CMS should work to have a smaller set of quality measures with some measures specific to the unique needs of each population served. As an ACO, we also would want to integrate community-based services that are run by the state and access state contracted rates. ACOs should have protection when a significant amount of care is delivered outside the service area regardless of the assignment/attribution model.

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

Yes, we should have the option to do this; however, it should not be required. Our ACO

would like to have the flexibility to test different models, including models sponsored by CMS or the ACO.

E. **Multi-Payer ACOs** – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs? Use any regulatory means available.
2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

CMS could convene experts to set up a standard quality measures set with specifications that all payers and CMS could select from for their contractual set of measures.

Billings Clinic

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February 27, 2014

Submitted via email to: PioneerACO@cms.hhs.gov

RE: RFI: Evolution of ACO Initiative at CMS

Dear Sir:

Thank you for the opportunity to provide input on policy considerations for the next generation of Accountable Care Organization models.

Billings Clinic is a physician-led health care organization, consisting of a multi-specialty physician group practice, a 285-bed hospital, and a 90-bed skilled nursing and assisted living facility. Billings Clinic employs over 3,700 full and part-time employees, including 255 physicians and 85 physician assistants and nurse practitioners on staff. Our organization includes partnerships with 11 critical access hospitals serving communities in Montana, Wyoming and the western Dakotas.

Our vision is Billings Clinic will be a national leader in providing the best clinical quality, patient safety, service and value. In support of this vision, Billings Clinic has been committed for many years to participation in national collaboratives and demonstration programs with both public and private payers.

Our comments are informed by approximately eight years of experience in the early models of Medicare ACOs—the Physician Group Practice Demonstration, 2005-2010 and the Transition Demonstration, 2011-2-12—and our current participation in the Medicare Shared Savings Program.

Section 1: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters.

1A. Would additional health care organizations be interested in applying to the Pioneer ACO Model?

Billings Clinic has determined that given our smaller population base and rural geography and aggressive risk arrangements we are unable to reach the minimum 15,000 beneficiaries to participate in the Pioneer ACO Model.

Beyond the information requested in the RFI, we would like to offer some additional suggestions for refinement in the ACO payment model that we believe would address known issues and encourage increased participation in ACOs.

Minimum Savings Rate

Under the law, CMS established a Minimum Savings Rate (MSR) for ACOs to account for the potential random variation in savings that may not be linked to improvements in quality and efficiency. The MSR is determined by the number of beneficiaries assigned to an ACO, and runs from a minimum of 2 percent to 3.9 percent for MSSP participants in both ACO tracks. While

we understand the concept of random variation, the MSR continues to serve as a strong disincentive for providers to enroll in the ACO program. This is particularly true for smaller ACOs or even sophisticated integrated delivery systems in rural areas that have small numbers of Medicare beneficiaries. Further, as ACOs are required to take risk, the need to account for random variation is eliminated or at least, greatly minimized. Meeting quality metrics also minimizes the impact random variation may have. The MSR, when coupled with risk adjustment scores that cannot increase, force ACOs to meet increasingly difficult savings margins. Given the investment ACOs must make to successfully manage a patient population's care, the MSR serves only to dissuade providers from becoming accountable and hampers the goals of CMS and Congress to transform the delivery system. We believe the MSR needs to be minimized as much as possible during the performance years and eliminated once an ACO takes risk. An alternative would allow CMS to perform a cumulative review of savings. If an ACO saved 1% each year over the 3 years, the chances that the improvement was random are virtually eliminated.

Risk Adjustment

Accurate risk adjustment is an important aspect of the evaluation of an ACO's performance. At present, the CMS HCC prospective risk scores may be lowered if the ACO's continuously assigned patient population shows an improvement in health status or if coding is not maintained at its prior level. Conversely, HCC scores are not increased if that same population becomes sicker or if an ACO increases its coding level. This leads to a scenario where historical benchmarks can only decrease and ACOs are left to chase a dropping reimbursement figure. As a result of this recalculation, many ACOs lost shared savings on their interim payment calculation.

We understand the concern that ACOs might utilize more accurate coding to augment risk scores and increase expected cost for a given patient population. However, we do not believe the answer to the problem is to cap HCC scores. If an ACO's patient population's HCC scores increase, CMS needs to adjust for the health status of this population using the higher risk score. Alternatively, Congress and CMS could allow ACOs to choose to use historical cost as the only determinant for the benchmark for the continuously assigned population. CMS has supported that method in the past. We also recommend creating a CMS/ACO task force to more fully consider this issue.

Quality and Financial Benchmarks

We suggest a requirement that the setting of quality and financial benchmarks are completed and publically reported prior to the beginning of the performance year. Currently, the program utilizes a dynamic methodology where the benchmarks are adjusted throughout the performance year. This approach magnifies the challenges for ACOs to set performance goals and track progress throughout the year.

The use of national expenditure growth trends for benchmarking may inadequately reflect costs (or savings) that are out of the ACO's control. More important than the growth trend is the

method used to determine the unadjusted benchmark. Establishing the benchmark using historic (local) cost data discriminates against historically efficient providers and will dissuade those providers from ACO participation. A better system would establish a combination of two financial performance goals: 1) an improvement goal (i.e., how well the ACO performs compared to the ACO beneficiaries' historic costs), and 2) an achievement goal (i.e., how well the ACO performs compared to national costs). With this combination method, ACOs remain accountable for continuously reducing costs, yet may be rewarded for historic efficiency.

Another issue of great concern to ACOs is the use of flat percentages for meeting quality benchmarks, rather than empirical data sources. Currently, nearly a third of the 33 quality measure thresholds employ flat percentages, rather than being based on actual Medicare program data.

Timeliness/Quality of Data from CMS

Accurate and timely performance data are critical for ACO success. However, even if sophisticated data are available, rural systems may not have the data analytic capacity necessary for advanced population health and cost management. Questions from ACOs regarding data analysis challenges should initiate CMS technical assistance and tool development to assist ACOs translate data into insight that improves care and lowers cost.

In conclusion, as an early adopter, we believe that if the Center for Medicare and Medicaid Services (CMS) desires to increase participation in ACOs, they will need to address the issues identified by current participants seeking to be sharing financial risk and successful in delivering high quality health care.

Sincerely,

Kristianne B. Wilson

Kristianne B. Wilson
Executive Director, Health Policy

Biotechnology Industry Organization

VIA ELECTRONIC SUBMISSION

March 1, 2014

Patrick Conway, M.D.
Deputy Administrator for Innovation and Quality
Chief Medical Officer
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
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RE: Request for Information: Evolution of ACO Initiatives at CMS

Dear Dr. Conway:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments regarding the Request for Information (RFI) on the "Evolution of ACO Initiatives at CMS" released by the Center for Medicare and Medicaid Innovation (CMMI) on December 20, 2013.[1] BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we closely monitor payment policies for their potential impact on innovation and patient access to drugs and biologicals. BIO believes that ACOs have great potential to provide better care for individuals, better health for populations, and lower growth in overall expenditures—a three-part aim that BIO fully supports. That said, risk-based models, particularly those involving capitated payment rates, create incentives to undersupply services to control spending, to the potential detriment of patients. BIO is particularly sensitive to the fact that one area in which care is stinted and services undersupplied is with regard to new technologies because the savings associated with these technologies often are not realized within the relevant window of time and their costs are not included in the benchmark. Moreover, while BIO applauds CMMI for seeking public input with respect to the Pioneer ACO program, BIO is concerned that CMMI aims to expand the program after obtaining only limited savings in the first two years, particularly after nine ACOs recently left the Pioneer demonstration.

[1] Center for Medicare and Medicaid Innovation, Request for Information: Evolution of ACO Initiatives at CMS (Dec. 20, 2013), available at: http://innovation.cms.gov/Files/x/Pioneer-RFI.pdf.

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To address these and other concerns, we believe that CMMI should take steps to ensure that the Pioneer ACO demonstration incentivizes participants to reap savings through the provision of better, more coordinated care, rather than by restricting patient access to care covered under Medicare or avoiding high-risk beneficiaries. BIO's concern is not only that patients have access to the novel therapies that may be the best treatments for their conditions, but also that the incentive to create new therapies is not diminished by the lack of uptake by entities involved in risk-based arrangements, including Pioneer ACOs. While the majority of our comments respond specifically to CMMI-posed questions, BIO makes additional recommendations in line with CMMI's overarching goal of improving quality, efficient patient care, including that ACOs should serve as the first step toward bringing new clinical innovations to patients by actively participating in clinical trials.

I. What are the Potential Benefits/Risks of Paying ACOs on a Capitated Basis akin to the Medicare Advantage (MA) Program? (Section II(A), Question 1)

As CMS has recognized in the context of the Medicare Shared Savings Program (MSSP), in any risk-based arrangement, providers of services and suppliers have a stronger incentive to control spending and achieve efficiencies, including to "stint on care and undersupply services."[2] This risk would only be exacerbated by moving from the double-sided risk model currently employed under the Pioneer ACO demonstration to payment on a capitated basis. Accordingly, CMMI would need to address how a fully capitated model would integrate existing cost-sharing requirements and whether a capitated model would maintain incentives put in place to provide certain types of care (e.g., preventive services) or to provide care to certain at-risk populations (e.g., influenza vaccines for the Medicare-age population). While the establishment of robust, evidence-based quality metrics can mitigate this risk, CMMI has yet to comprehensively address the concerns that the current quality outcomes metrics are flawed, as discussed in greater detail in Section X, below.

II. What Categories of Spending Should ACOs at Full Insurance Risk be Responsible For? (Section II(A), Question 2)

BIO believes that, to the extent ACOs have only partial responsibility for the care of beneficiaries, they may have incentives to shift patient care towards those areas for which they are not responsible. For instance, when the ACO is not responsible for both Part B and Part D spending, there is the potential that providers will unduly rely on prescription medications reimbursed through the non-included Medicare program, namely Medicare Part D, over other forms of care. These concerns are exacerbated by the recently proposed changes to narrow and even eliminate crucial protections under the current Medicare Part D protected class policy, which afford the most vulnerable patients more robust and timely access to the drugs they need in the settings most appropriate for them.

This "gaming of the system" can also cause a shift in the site of care that significantly impacts patients' ability to receive care in the most appropriate or convenient setting, which

[2] 76 Fed. Reg. 19,528, 19,617 (April 7, 2011).

in turn can impact adherence to treatment and short- and longer-term health outcomes.[3] Any financial incentives that inappropriately influence the selection of treatment options are problematic, not only because of the access to quality care issues they may create, but also because they may cause patients to incur additional out-of-pocket costs, which in turn can also impact prescription drug adherence and ultimately, clinical outcomes.

From the perspective of the Medicare program, it is also problematic to reward ACOs for "paper savings" achieved through cost-shifting. Therefore, CMS should actively monitor ACOs to ensure that patients continue to receive the most appropriate therapy from these ACOs. Such measurement should be ongoing, and the need for any changes to the program to improve patient access to the most appropriate therapies should be identified, and remedies evaluated, through notice-and-comment rulemaking. Moreover, to the extent that ACOs are at full insurance risk for additional categories of spending (e.g., Part D, Medicare/Medicaid dual-eligibles, Medicaid), the agency must ensure that ACOs are adequately reimbursed for these costs to avoid disincentivizing the use of new technologies and those treatments that may be more expensive over a short timeframe but yield significant benefits to the patient over the longer-term.

III. Are there Services that Should be Carved out of ACO Capitation? (Section II(A), Question 3)

As noted above, a risk-based program, such as the Pioneer ACO demonstration, increases the incentives to "stint on care or undersupply services." BIO is sensitive to the fact that one area in which care is stinted and services undersupplied is with regard to new technologies. This is because the savings associated with these technologies often are not realized within the relevant window of time and their costs likely would not be included in the benchmark. In fact, recent research illustrates that ACOs are not currently able to demonstrate the value of appropriate medication use to decrease overall costs and increase care quality, raising questions of the appropriateness of including prescription drugs within any capitation demonstration before these capabilities are improved.[4] Additionally, to the extent that ACOs are paid on a capitated rate based on a prior trend, innovative technologies specifically are highly unlikely to be adequately captured by that capitated fee, as utilization of new technologies and novel medical breakthroughs is very difficult to predict on a facility level with enough granularity to ensure fair measurement. Consequently, ACOs would effectively not be reimbursed to the extent their patients obtain these items and services.

As evidenced by the Food and Drug Administration's (FDA's) new focus on breakthrough therapies, we are in an era of new and important discoveries for the treatment of human diseases. To ensure that patients continue to have access to innovative medical technologies, including drugs and biologicals, BIO strongly urges CMMI to incorporate protections added by Congress to the Medicare program more broadly by creating a carve-

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[3] As recently as February 2014, the Department of Health and Human Services (HHS) Office of Inspector General identified evidence of site-of-care shifts due to financial incentives, *see* HHS OIG. 2014 (February 20). *Medicare and Beneficiares Could Realize Substantial Savings if the DRG Window Were Expanded*. OEI-05-12-00480. Washington, DC: HHS OIG, Available at: http://oig.hhs.gov/oei/reports/oei-05-12-00480.pdf.

[4] Dubois, R.W., M. Feldman, A. Lustig, G. Kotzbauer, J. Penso, S. D. Pope, and K. D. Westrich. 2014. Are ACOs Ready to be Accountable for Medication Use? *Journal of Managed Care Pharmacy* 20(1):17-21a.

out for new, innovative medical technologies from both the shared savings calculations and capitated payment rates for Pioneer ACOs. With such a carve-out, the decision to use promising new therapies will not affect the calculation of ACOs' expenditures for purposes of determining whether they generated shared savings. Moreover, ACOs would not be penalized when a new technology is approved mid-year that was not contemplated in the calculation of its capitation rate.

There are a number of ways that CMMI could implement this carve-out. One way would be to rely on the existing mechanisms for pass-through status under the hospital Outpatient Prospective Payment System (OPPS). When a drug or biological receives pass-through status, CMS necessarily has made a determination that it is a new technology, the costs of which are not insignificant in comparison to the payment for the procedures or services associated with its use.[5] It, therefore, would be appropriate to exclude all of the expenses related to both of these types of new technologies from the expenditures that are used to determine an ACO's eligibility for shared savings to ensure there is no disincentive for their use in an ACO.[6]

By structuring the carve-out in this way, only those ACOs with expenses for new technologies and innovative therapies would receive an adjustment to their performance years. These types of policies would not penalize ACOs that incorporate Centers of Excellence and other entities and provider groups that have traditionally been early adopters of novel treatments and therapies, but would still provide these entities with incentives for appropriate utilization of important advances in therapy.

In addition to important advances in therapies, BIO also encourages CMMI to consider carving-out certain existing therapies, namely those that may be particularly vulnerable within a full insurance risk model based on the small number of patients who may need it, disease severity, and the cost of providing such care. For instance, hemophilia factor products—used to treat rare bleeding disorders such as Hemophilia A, Hemophilia B, and Acquired Hemophilia—are used by a relatively small population but to significant, life-sustaining effect. Patients with severe hemophilia produce less than one percent of the normal amount of the affected clotting factor and are dependent on factor from infusions to treat or prevent bleeding episodes. Including hemophilia factor products in an ACO's capitated rate may significantly disadvantage access to these products because of the impact it could have on an ACO's shared savings calculation, especially for smaller ACOs. This, in turn, would further exacerbate the perverse incentives already in play to stint on or undersupply care, or otherwise discriminate against these patients. Therefore, to further ensure some of the most vulnerable patients have access to the most appropriate care, we encourage CMMI to consider carving-out, or otherwise providing equivalent protections for, existing therapies such as these.

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[5] SSA § 1883(t)(6)(A)(iv)(II).

[6] Although pass-through status applies only in the hospital outpatient department setting, this carve-out should apply regardless of the care setting, including drugs and biologicals furnished in the physician office setting, which could be identified through the use of the two miscellaneous J-codes. Such congruity is necessary to ensure that the policy does not create an incentive to perform procedures in the hospital rather than physician office.

IV. What Key Elements of the Regulatory and Compliance Framework for MA Should be Adopted for ACOs Assuming Full Insurance Risk? (Section II(A), Question 5)

As noted above, BIO is very concerned that the transition to full insurance risk may further incentivize providers to restrict or limit patient access to the most appropriate care, or for ACOs to cherry-pick the healthiest patient populations. To mitigate these incentives, we strongly urge CMMI to incorporate into any future phase of the Pioneer ACO model—whether it includes the assumption of full insurance risk or another structure for risk-based reimbursement—several of the patient protections that have helped counteract these pressures under the MA program for decades. Specifically, we believe that the Pioneer ACO model should incorporate each of the following protections:

- **Anti-Discrimination Protections:** In light of the potential for adverse selection in the Pioneer ACO program, particularly under a capitated fee arrangement, BIO urges CMMI to incorporate the MA requirements aimed at preventing patient discrimination. For instance, CMMI should adopt the beneficiary protections outlined at 42 C.F.R. § 422.110(a), under which ACOs would be prohibited from denying, limiting, or conditioning benefits to beneficiaries on the basis of factors such as medical condition, claims experience, medical history, and genetic information. Relatedly, we also urge CMMI to consider incorporating the MSSP's tough sanctions for avoidance of at-risk beneficiaries.[7]
- **Ensure Access to Medically Necessary Care:** Because capitated payments raise the risk of ACOs restricting patient access to medically necessary care, we believe that CMMI should incorporate certain MA protections aimed at ensuring access to these services, including access to a diverse provider network, discussed in more detail below. For instance, CMMI should establish a review process under which the agency ensures that beneficiaries receiving care from Pioneer ACOs continue to have access to the basic Medicare benefits. CMMI may look to the process outlined at 42 C.F.R. §§ 422.100-101 as a model for this review.
- **Establish a Robust Appeals and Grievance Process:** To ensure that beneficiaries are not adversely affected by the ongoing demonstration, CMMI should establish a robust beneficiary appeals process available to beneficiaries whose providers are participating in Pioneer ACOs. This process, which could be modeled on the process that is provided for beneficiaries enrolled in the MA program,[8] would provide a mechanism for beneficiaries who believe they are being denied access to appropriate care as a result of their provider's participation in an ACO to raise those concerns and receive a decision relating thereto. Although BIO recognizes that beneficiaries who are dissatisfied with their care are not bound to the ACO, this grievance process will provide recourse for beneficiaries who do not want to change their provider, but who believe that the provider's participation in the ACO is affecting the care that he or she is receiving. In implementing this recommendation, BIO urges CMMI to consider approaches to improve upon existing challenges with delays in the MA and traditional Medicare appeals processes. In addition, for

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7 See 42 C.F.R. § 425.316(b).

8 See Medicare Managed Care Manual, Ch. 13, §§ 10.1, 10.3.1.

patients for whom the appeals process would be inappropriate (e.g., because they are not seeking to have a certain decision reversed, but rather have more generalized complaints), CMMI should establish a grievance mechanism, such as an ACO ombudsman. This ombudsman would receive beneficiary and provider complaints and provide valuable feedback to CMMI on how the Pioneer ACO program is being operationalized and areas that the agency may need to address in future rulemakings or other guidance. Relatedly, CMMI should require ACOs to provide meaningful inclusion of patients in the ACO governance structure.

- **Prevent Interference with the Practice of Medicine:** BIO is also very concerned that efforts to obtain shared savings (and avoid shared losses) within the Pioneer ACO demonstration may cause ACOs to exercise undue influence over the practices of their participating providers (e.g., in attempts to better regulate utilization of services). Similarly, moving to a full insurance risk model may introduce financial incentives into the clinical decision-making process, including prescribing decisions, that may negatively impact patients' access to the therapies and services that are most appropriate for them individually as expressly covered by Medicare. Accordingly, we urge CMMI to prohibit ACOs from interfering in health care professionals' advice to beneficiaries (42 C.F.R. § 422.206), or from making shared savings payments to physicians as an inducement to reduce or limit medically necessary services (42 C.F.R. § 422.208(c)). We also believe that affording participating providers with a key role in the development of ACO policies and procedures will ensure that their medical decision-making is not unduly restricted, and thus urge CMMI to adopt protections akin to 42 C.F.R. § 422.202, under which ACOs would be required to create a formal mechanism to consult with providers regarding the organization's medical policy, quality improvement programs, and medical management procedures. Finally, a robust process must be in place for providers to quickly appeal the coverage decisions of the ACO on the basis of clinical appropriateness for an individual patient. CMMI should therefore consider setting minimum standards and timelines for participants' review processes and give stakeholders the opportunity to provide meaningful input into those minimum standards.
- **Prohibit Excessive Beneficiary Cost-Sharing:** It is not clear from publicly available documentation regarding the current operation of the Pioneer ACO demonstration how beneficiary cost-sharing will be calculated for services for which Pioneer ACOs are paid on a capitated basis. To the extent that ACOs are given flexibility in this regard, we urge CMMI to ensure that such cost-sharing conform to MA cost-sharing protections outlined under 42 C.F.R. §§ 422.100 and 422.105. Otherwise, we are concerned that aligned beneficiaries will end up paying more out-of-pocket than beneficiaries receiving care outside the Pioneer ACO demonstration.
- **Protect Beneficiary Confidentiality:** Given the need for data sharing within the Pioneer ACO demonstration, BIO is concerned that patients' personal information, including medical history, may not be adequately protected. Therefore, we urge CMMI to require ACOs to ensure the privacy and confidentiality of patient records (42 C.F.R. § 422.118).
- **Encourage Participation by a Wide Range of Providers:** In order to ensure that patient care is adequately coordinated by the ACOs, it is essential that the ACOs include a wide array of participating providers, including medical specialists. In a full

insurance risk model, there is a specific concern that providers may be assessed for inclusion in an ACO based on economic criteria rather than on their ability to provide vital, quality services to a patient population. Therefore, BIO urges CMMI to require ACOs to provide access to appropriate providers and services (42 C.F.R. §§ 422.112-114), to meet certain requirements with respect to provider selection and credentialing (42 C.F.R. § 422.204), and to require ACOs to include a role for specialists in leadership and management. CMMI should also require ACOs to make certain disclosures to "aligned" beneficiaries, including with respect to the number, mix, and distribution of participating providers (42 C.F.R. § 422.111).

In addition to the need for patient protections, BIO is concerned that changes in policy or the arrival of a new innovative therapy would impose costs on Pioneer ACOs not included in their capitated rates, incentivizing the ACOs to restrict patient access to this care based on financial, rather than clinical, considerations. Accordingly, we urge CMMI to adopt a policy akin to that outlined at 42 C.F.R. § 422.109, under which ACOs would not be required to assume risk for the costs associated with a mid-year National Coverage Determination (NCD) or legislative change that imposes costs not included in that year's capitated rate. We believe that this policy should also be expanded to account for newly approved technologies that are not yet included in the capitated rate.

V. What are the Advantages and Disadvantages of Different Strategies for Risk Adjustment? (Section II(A), Question 9)

As you are aware, risk adjustment serves to correct for market imbalances that occur if an insurer (or, in this case, ACO) differentially attracts pools of beneficiaries whose medical costs diverge from the market-wide average. The need for this adjustment arises from the skewed nature of health risk: the top 20 percent of the population accounts for about 80 percent of total spending, and the very highest medical costs are concentrated in the top one percent.[9] In the absence of risk adjustment, those ACOs that attract more than their share of these high-cost beneficiaries will be penalized—both in terms of their shared savings calculation and capitated rate—particularly to the extent ACOs are prohibited from avoiding high-risk beneficiaries, as we recommend in Section IV, above.

There are two basic measures to assess health risk for purposes of risk adjustment: demographic and medical. BIO strongly urges CMMI to adopt a risk-adjustment methodology that is based on medical factors, as risk adjustment based on demographic factors alone is insufficient. Indeed, a study conducted by Jonathan Weiner of the Johns Hopkins University found that the best diagnosis-based adjuster is about five times more accurate than demographic adjustment.[10] Moreover, using encounter-based diagnostic information for this purpose is generally feasible for all types of health plans. For instance, risk adjustment based on medical factors is used for all Medicare Advantage and many

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[9] Conwell LJ, Cohen JW. Characteristics of people with high medical expenses in the U.S. civilian noninstitutionalized population, 2002. Statistical Brief #73. March 2005. Agency for Healthcare Research and Quality, Rockville, MD. Web site: http://meps.ahrq.gov/mepsweb/data_files/publications/st73/stat73.pdf.

[10] This study randomly assigned 50,000 members to 25 hypothetical health plans to determine which risk-adjuster (medical v. demographic) would overpay the lowest-risk plan or underpay the highest-risk plan). See J.P. Weiner, A. Dobson, S.L. Maxwell et al., "Risk-Adjusted Medicare Capitation Rates Using Ambulatory and Inpatient Diagnoses," *Health Care Financing Review*, Spring 1996 17(3):77-99.

Medicaid patients nationwide.[11] Not to mention that collecting these data may assist ACOs in performing other necessary tasks, to include care coordination and performance on quality measures.

One strategy that CMMI may consider for this purpose is adopting the diagnosis-based risk-adjustment methodologies employed in the MA and Part D programs. For instance, CMMI could make retrospective adjustments to capitated payment rates made to ACOs based on health status, akin to the procedure used for Medicare Part D plans pursuant to 42 C.F.R. § 423.343(b).

On a related note, BIO is concerned that two strategies used to calculate shared savings under the Pioneer ACO demonstration do not adequately take into account risk. First, BIO is concerned that the lack of risk adjustment for diagnoses occurring during the performance period creates a disincentive to provide a transplant. Increasing transplants is an objective of the Department of Health and Human Services (HHS). In fact, each year, HHS recognizes hospitals and healthcare providers with awards for increasing transplantation. Although BIO understands the use of the CMS-HCC (Hierarchical Conditional Categories) risk-adjustment model, it is our understanding that there are difficulties with using the HCC model to adjust for risk associated with transplants, particularly for non-kidney transplants. Furthermore, the risk associated with transplants could pose a particular problem for ACOs, given that they will likely treat relatively small populations, where a single transplant could cause a significant shift in their per-beneficiary expenditures. If the HCC model does not predict for risk associated with all types of transplants, ACOs will have a very strong incentive to avoid patients in need of transplants or to defer offering a transplant. BIO therefore recommends that CMMI remove expenses attributable to organ acquisition, transplants, and drugs provided for ensuring acceptance of the donor organ when calculating expenditure amounts in both the benchmark and performance years.

Second, BIO is concerned that the outlier threshold used for this purpose is too high, requiring ACOs to potentially bear the risk of extraordinarily high-cost beneficiaries. As you are aware, as with the MSSP, for purposes of calculating shared savings under the Pioneer ACO demonstration, ACOs have the option to truncate an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile for each benchmark and subsequent performance year.[12] BIO appreciates that CMMI has taken this step to take into account outliers that would skew an evaluation of an ACO with regard to generated savings. We think it also aligns well with the goal of protecting beneficiary access to innovative new therapies. However, BIO believes that the value of the expenditure cut-off—both for protecting ACOs from the variation associated with

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[11] See, e.g., G.C. Pope, J. Kautter, R.P. Ellis et al., "Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model," *Health Care Financing Review*, Summer 2004 25(4):119-41, available at: http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/04Summerpg119.pdf; R. Winkelman and R. Damler, *Risk Adjustment in State Medicaid Programs* (Jan. 2008), available at: http://www.soa.org/library/newsletters/health-watch-newsletter/2008/january/hsn-2008-iss57-damler-winkelman.pdf.

[12] CMMI. 2011. *Pioneer ACO Alignment and Financial Reconciliation Methods v.7.1*. pp.12-13. Baltimore, MD, CMS, Available at: http://innovation.cms.gov/Files/x/Pioneer-ACO-Model-Benchmark-Methodology-document.pdf.

catastrophically large claims and for protecting beneficiaries from the incentives an ACO may have under the Pioneer ACO program to avoid using new medical therapies—would be stronger if the threshold were lower. Therefore, BIO recommends that CMS lower the expenditures threshold cut-off to the 95th (rather than 99th) percentile for all ACOs.

VI. What are Potential Program Integrity Issues that ACOs Transitioning to Full Insurance Risk May Encounter and what are Appropriate Preventive Safeguards? (Section II(A), Question 11)

The principal area in which BIO believes that the transition to full insurance risk under the Pioneer ACO demonstration poses a program integrity risk relates to the diversion of drugs and biologicals under the 340B Drug Pricing Program. As you are likely aware, pharmaceutical manufacturers that want their products to be reimbursed with federal funds under Medicaid are required to participate in the 340B Program and sell their covered outpatient drugs to 340B "covered entities" at deeply discounted prices.

To safeguard against the potential for diversion of drugs purchased with such discounts, Congress specifically prohibited the resale of drugs purchased by these covered entities "to a person who is not a patient of the entity."[13]

In 1996, the Health Resources and Services Administration (HRSA)—the agency charged with administering the 340B Program—issued final guidance regarding the definition of "patient" for this purpose.[14] This definition is very broad and, in 2007, HRSA issued a notice regarding proposed clarifications to the definition in response to rising concerns that "some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications under the 340B Program."[15] That guidance was never finalized, and in fact it was later rescinded, effectively compelling covered entities to return to relying on the 1996 "patient" definition. In January 2011, HRSA submitted two notices to the Office of Management and Budget (OMB), to issue a new notice on the "patient" definition. OMB has completed its review of this notice, but it has not been published to date.

For years, BIO has expressed its concern about the way in which the lack of a robust patient definition has led to significant enforcement challenges and the extension of discounted drug pricing to individuals and entities that BIO does not believe either Congress or HRSA intended to receive it. In the absence of a new patient definition, BIO is concerned that ACOs may seek to inappropriately gain access to the discounted drug pricing available to patients of a 340B covered entity when 340B covered entities are included in the ACO. In particular, we are concerned that the requirement that ACOs coordinate and integrate care will lead the ACO and 340B covered entity to conclude that a patient of the ACO is a patient of the 340B covered entity, even if the patient does not otherwise meet the definition of a 340B patient, for purposes of obtaining discounted drug pricing. The potential for such abuse undermines the integrity of the 340B program and threatens the goals it is intended to achieve, as well as that of the Pioneer ACO demonstration.

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13 42 U.S.C. § 256b(a)(5)(B).
14 61 Fed. Reg. 55,156 (Oct. 24, 1996).
15 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007).

To address this issue, BIO urges CMMI to use its authority under section 1899(a)(1)(A) of the Social Security Act to impose program integrity criteria to protect the Pioneer ACO program from fraud and abuse related to the 340B Program. Specifically, CMMI should prevent ACOs that affiliate with 340B covered entities from diverting products under the 340B Program. This aligns with 2012 HRSA guidance that states that "inclusion of a covered entity within an ACO does not make the entire ACO eligible for receiving discounted drugs under the 340B Program and does not permit ACO associated entities, which do not satisfy the eligibility requirements of section 340B(a)(4), to access 340B Program discounted drugs."[16] BIO also encourages CMMI to work with HRSA to provide the additional guidance necessary to minimize the opportunity for product diversion and to ensure that the 340B covered entities that enable product diversion, including the ACOs in which they participate, are held accountable. This is especially important given the concerns recently raised by the HHS Office of Inspector General that: a lack of clarity on HRSA's definition of a 340B-eligbile "patient" has led to the inconsistent assessment of eligibility at the contract pharmacy level; and that most covered entities do not employ oversight activities in compliance with HRSA's recommendations.[17] With the rise in the number of covered entities that employ contract pharmacies, and the sheer number of contract pharmacies emerging, coordination between CMMI and HRSA will be crucial to ensure the integrity of the interaction between ACOs and the 340B program.

On a related note, BIO urges CMMI to ensure that ACOs are not unjustly enriched for products purchased through the 340B program. Specifically, we believe that CMMI should adjust the capitated rate paid to ACOs that include 340B "covered entities" downward to account for the discounted drugs obtained under the 340B program. Otherwise, these entities would obtain an unfair advantage over ACOs that do not include such covered entities, potentially causing perverse incentives with respect to the 340B program and participation in the Pioneer ACO demonstration.

VII. Integration of Medicare Part D (Section II(B))

As we have previously noted, BIO believes that the shared savings calculation should incentivize ACOs to generate "savings" that reflect real quality and efficiency gains and are not the result of gaming or cost-shifting. If CMMI includes Part D expenditures in the calculation to achieve this aim, we urge that all Part D beneficiary protections similarly convey, including, but not limited to:

- **Protecting patients' access to appropriate therapies through minimum formulary requirements**: CMMI should include the statutory formulary review and transparency requirements included in the Part D regulations at 42 C.F.R. § 423.124. Pioneer ACOs should adhere to all requirements associated with pharmacy and therapeutic committee review, composition, and decision-making. While Pioneer ACOs should also be required to meet the Part D minimum inclusion standard for drugs and biologicals, the number and type of covered therapies should not be

[16] HRSA. 2012 (May 23). 340B Drug Pricing Program Notice Release No. 2012-2.
[17] HHS Office of Inspector General (OIG). 2014. *Contract Pharmacy Agreements in the 340B Program*. Washington, DC: HHS OIG, Available at: https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp.

allowed to be revised downward from those currently included when meeting this minimum standard. CMMI should also review the beneficiary transition process to ensure patients will be able to access appropriate therapies during and after any inclusion of Part D expenditures in the shared savings and benchmark calculations.

- **Ensuring out-of-network-access to appropriate therapies**: Though beneficiaries are able to opt-out of receiving care from a Pioneer ACO entirely, protections must be in place for those who want to remain a part of this primary care collective but may need to obtain some portion of their therapies outside of it (e.g., based on where they live or work). To ensure these patients are able to retain this option, CMMI should require Pioneer ACOs adhere to the same standards as Part D sponsors in providing out-of-network pharmacy access to covered drugs without excessive cost-sharing (42 CFR § 423.124).
- **Patients must be able to access covered drugs conveniently**: To ensure equal accessibility of Part D-covered drugs by Pioneer ACO patients, CMMI should require Pioneer ACOs to meet the same requirements as Part D sponsors in securing sufficiently broad participation in their pharmacy networks (excluding mail-order pharmacies) to ensure convenient access to covered drugs.[18]

BIO believes that including these beneficiary protections is crucial to any effort to incorporate Part D expenditures into the sharing savings calculations of Pioneer ACOs.

In considering the integration of Part D expenditures in the ACO model, CMMI must address issues around cost-sharing and utilization-management techniques already employed by Part D prescription drug plans. Under a full insurance risk model—without adequate out-of-pocket cost restrictions and cost-sharing limits built into benefit design requirements—ACOs may be incentivized to shift more and more costs to patients through higher copays and coinsurance to drive down their recorded contribution to the entities' spend. This would directly and significantly increase the burden on patients, negatively impacting patient access to the treatments most appropriate for them and patient adherence to those treatments, especially with respect to those treatments that require a longer course. ACOs may also be incentivized to increase their use of utilization-management techniques, like fail-first protocols and step therapy, to deter patients from higher-cost therapies regardless of their clinical benefits. Thus, if CMMI decides to pursue the integration of Part D expenditures in the ACO model, it must simultaneously include all current out-of-pocket cost limits, require robust exceptions and appeals processes, and actively monitor for increased use of discriminatory utilization management practices. These protections are necessary to ensure that an institution's financial incentives are not impacting patients' timely access to the therapies most appropriate for them.

Finally, CMMI should not alter the current market-based process by which the Part D program operates, as doing so risks perverting the incentives in the Part D program that have made it successful to-date in providing seniors with affordable prescription drug plans. Any effort by CMMI to incorporate Part D into the Pioneer ACOs' demonstration project must therefore protect the robust private competition that has kept the Part D program working well to generate lower costs for seniors, while providing broader choice for enrollees. The

[18] Medicare Prescription Drug Benefit Manual (MPDBM), Ch. 5 v.09.20.11, 50.

success of this market-oriented program is evidenced by the stability of the average beneficiary premium (which has remained at approximately $31 for the last four years) [19] and overwhelming support—as high as 90 percent—by seniors.[20] Accordingly, we strongly urge CMMI to continue to rely on the current Part D bidding process, instead of creating a unified expenditure target, as it represents a successful market-oriented approach to ensuring timely patient access to innovative therapies.

VIII. Integration of Medicaid (Section II(C))

As noted above, BIO is concerned about CMMI expanding the scope of the Pioneer ACO program to include additional ACOs, given that the program has not uniformly shown cost savings and that many ACOs recently left the program. This same concern applies to the inclusion of additional covered lives, particularly Medicaid beneficiaries.

The Medicaid program is quite complicated and Medicaid beneficiaries, including dual-eligibles, tend to be sicker and more vulnerable than individuals covered by Medicare or private insurance. With this in mind, CMMI is also operating duals demonstrations in a handful of states, through which states are experimenting with ways to better coordinate care for this population. CMMI and the states have not yet demonstrated an ability to launch these programs successfully, so further incorporating these populations seems premature. Rather, CMMI should wait to obtain results from the duals demonstrations before incorporating duals into the Pioneer ACO program.

If CMMI nonetheless moves forward with this suggestion, the agency should take care to limit the participation of Medicaid beneficiaries in the demonstration to a small sub-population. Otherwise, CMMI runs the risk that, between the duals and Pioneer ACO demonstrations, so many dual-eligibles will be involved in some type of demonstration initiative, such that there will essentially be no "control" population against which to compare the results of these programs. We would also urge CMMI to take care to address the myriad of administrative issues associated with incorporating Medicaid beneficiaries into the Pioneer ACO demonstration, including ensuring that Medicaid drug rebates are not collected for non-Medicaid utilization within the ACOs.

IX. Other Approaches for Increasing Accountability (Section II(D))

CMMI identifies the potential to explore a "provider-led community ACO" model that would hold an ACO accountable for total Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) expenditures and quality outcomes for all Medicare, Medicaid, and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. BIO recommends that, in the development of such a model, CMMI closely coordinate with the House Committee on Ways and Means and Senate Committee on Finance, which identified the same model as a potential alternative to current policy in its

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[19] Department of Health and Human Services (HHS). 2013 (July 30). *Medicare drug premiums remain stable four years in a row*. Washington, DC: HHS, Available at: http://www.hhs.gov/news/press/2013pres/07/20130730c.html.

[20] Freeman, M. 2012. Survey: U.S. Seniors Overwhelmingly Satisfied with Medicare Part D Coverage. Medicare Today, Available at: http://www.krcresearch.com/pdfs/PART-D-R.pdf.

October 2013 Discussion Draft on SGR Repeal and Medicare Physician Payment Reform. We reiterate here the themes expressed in our comments in response to the high-level framework put forward by the Committees to CMMI: (1) any such model must improve patient access to high-quality care and require robust assessment and improvement efforts on a continuous basis; (2) the outcomes of current demonstration projects should be thoroughly evaluated before new models are attempted; (3) there must be in place mechanisms to support adoption of, and patient access to, newer tests and treatments that are recognized by providers and patients as important and promising advances; and (4) patients must retain the flexibility to choose providers and make treatment decisions that are most appropriate for them individually.

X. Multi-Payer ACOs (Section II(E)): Harmonizing Quality Measures and Interactions with Private ACOs

A. Harmonizing Quality Measures

As we noted in the first section of this comment letter, the establishment of robust, evidence-based quality metrics can mitigate the inherent disincentives to provide appropriate care caused by a risk-sharing reimbursement system. However, BIO believes that the quality metrics employed in the current Pioneer ACO demonstration project do not yet meet this standard.

For example, we are very concerned that CMMI has yet to comprehensively address the concerns that current quality outcomes metrics are flawed, voiced by then-Pioneer ACO participants in a February 25, 2013 letter to CMMI.[21] This letter expresses that there remains a need for "metric standards [that] support a level playing field", are precise, and shoot "for a uniform benchmark" that is realistic and fair; rely only on metrics that have a robust evidence-base for specific subpopulations (e.g., segregated by demographics); and that aggregation methodologies for composite metrics are logical and "carefully constructed". BIO supports these requests but remains unsure how they have been addressed in the time since the letter was sent. Accordingly, before expanding the current Pioneer ACO demonstration or establishing demonstrations of new ACO models, CMMI should meet the requests of current participants and release additional information on the performance and assessment of current metrics along with the input of current participants.

Because quality performance determines an ACO's eligibility for shared savings and the amount of shared savings to which it may be entitled, BIO also believes that it is especially important that the measures against which ACOs are measured are endorsed by a national organization, such as the National Quality Forum (NQF), or a disease or provider specialty society. There are a number of reputable national organizations that have sophisticated processes for developing and endorsing measures. In addition to the NQF, these include the National Committee for Quality Assurance (NCQA), the Joint Commission, the Centers for Disease Control and Prevention's Advisory Committee of Immunization Practices (ACIP), and the American Medical Association (AMA).

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[21] Letter from Pioneer ACOs to Rick Gilfillan, Hoangmai Pham. 2013 (February 25). Available at: http://www.washingtonpost.com/blogs/wonkblog/files/2013/03/2013-Quality-Benchmarks.pdf.

Furthermore, to ensure that Pioneer ACOs are not required to adhere to outdated standards, we urge CMMI to institute a process for reviewing the existing measures and for updating or removing measures that are outdated on a timely basis, and in no event later than six months after the date at which the measure becomes obsolete. CMMI may also consider creating an exception process for providers who follow new guidelines or measures to avoiding hindering patient care when quality measures lag behind changes in treatment.

Once robust quality measures are defined, and a process for updating them has been put in place, BIO generally supports CMMI's aim to align these measures across initiatives and demonstrations—such as the Physician Quality Reporting System, Electronic Health Records Incentive Program, Hospital Inpatient Quality Reporting System, the Value-Based Payment Modifier, Medicaid, and even private sector initiatives—to decrease redundancy as well as the measurement and reporting burden on providers. In doing so, however, CMMI must take into account whether and how the current measures are able to sufficiently capture the benefits of appropriate use of drugs and biologicals with different populations. CMMI also should take into consideration that the impact of certain healthcare services may not be fully apparent even over a period of six months to a year. Accordingly, BIO recommends that the quality and cost of health care given by Medicare providers should be studied over a period of time sufficient to account for the full effect of longer-term treatments and therapies. Considering the longer-term impact of innovative drugs and biologicals, for example, is crucial to sustaining improvements in quality of care and decreasing overall costs.

Finally, BIO recommends that, to decrease the redundancy and burden of reporting multiple sets of measures, CMMI undertake more general efforts to consider what can be learned from the challenges and lessons obtained from different private ACO models, especially from the perspectives of providers and patients participating in those models. Additionally, BIO cautions that, while coordination is encouraged between all payers to minimize duplicative and burdensome requirements, a one-size-fits-all approach is not the answer to appropriately provide for the needs of such diverse provider and patient communities as those served by private insurance, Medicaid, and Medicare. To better ensure that robust quality measurement is leading to improved patient care and patient access to necessary and innovative therapies, CMMI should therefore engage with patients, providers, and other stakeholders through a formal rulemaking process to ensure included measures are scientifically and clinically relevant.

B. Improving the Regulatory Environment for Innovative ACO Models

BIO urges CMMI to take steps to give manufacturers and Pioneer ACOs greater flexibility to allow for innovative contracting models that better support integrated care. Such flexibility is also necessary to allow better harmonization of contract arrangements across federal integrated care models, which may currently present a barrier to participation.

From the point of view of manufacturers, certain contracting arrangements may not be pursued due to the financial risk and/or penalties they may generate, including in the context of operating these arrangements in compliance with existing federal price reporting requirements. For example, adding to the inherent uncertainty of entering into risk-sharing

arrangements in general, it is an open question how such arrangements between manufacturers and ACOs, or the component entities of ACOs, should be factored into the various price reporting requirements with which manufacturers must comply (e.g., Medicare Average Sales Price, Medicaid Best Price). To improve the regulatory environment for these innovative arrangements, BIO therefore recommends that CMMI engage with stakeholders to identify a process that allows manufacturers to exempt some or all of these arrangements from their price reporting obligations.

In the same vein, to improve the consistency of legal requirements across integrated care arrangements, we ask CMMI, in collaboration with the HHS Office of Inspector General (OIG), to use the authority under section 3021 of the ACA to issue waivers of the federal anti-kickback statute that cover participants in the Pioneer ACO demonstration, similar to the waivers that CMS and OIG issued for participants in the MSSP.[22] We also strongly urge CMMI to work with OIG and other stakeholders to explore the flexibility of extending such waivers to manufacturers that contract with ACOs and ACO provider/suppliers in the context of this demonstration on a case-by-case basis.[23]

XI. CMMI Should Require ACOs to Participate in Clinical Trials

While much of the RFI asks specific questions about the next phase of ACO models, it is clear that CMMI envisions that ACOs will become leaders in health care over the longer-term through improving on the current models to increase quality care and decrease overall costs. BIO believes that a third tenet of this goal should be improving access to care, which was one of the primary goals of CMMI's authorizing legislation, the ACA. This should be true not only for their use of innovative service delivery models, but also with regard to their diffusion of innovative technologies. To this end, BIO believes that ACOs should be involved in clinical trials, as they serve as the first step toward bringing new clinical innovations to patients.

CMMI could do this in one of two ways. First, CMMI could require ACOs to participate in clinical trials as a condition of participating in the Pioneer ACO program. BIO believes that such a requirement would not be overly burdensome on ACOs—particularly the sophisticated ACOs participating in the Pioneer demonstration—and would be consistent with the "three part aim." Alternatively, CMMI could award "bonus points" to ACOs that participate in clinical trials. These bonus points would be similar to the increase in the shared savings rate that CMMI is proposing to provide to ACOs that include Federally Qualified Health Centers or Rural Health Clinics in the ACO. Requiring or incentivizing participation in clinical trials not only will help to develop new breakthroughs in diagnostics, treatments, and cures for many of the most devastating diseases affecting millions of

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[22] ACA § 3021 (codified as SSA § 1115A(d)(1)) (permitting CMMI to waive provisions of title XI of the Social Security Act). See also 76 Fed. Reg. 67,992, 68,007 (November 2, 2011) ("[s]everal commenters inquired about the application of these waivers to ACO demonstration programs sponsored by the Innovation Center, including application to the Pioneer ACOs. The waivers in this IFC are promulgated under section 1899(f) of the Act and, as set forth in the statute, are limited to the Shared Savings Program. Section 3021 of the Affordable Care Act includes a similar waiver authority that may be exercised for Innovation Center demonstration programs, including the Pioneer ACOs. We will address the exercise of that waiver authority in guidance relevant to those programs. As noted previously in this IFC, the waivers in this IFC will apply to ACOs participating in the Advance Payment Initiative because those ACOs also participate in the Shared Savings Program.").

[23] 76 Fed. Reg. at 68,001.

Americans, but also will solidify the role of ACOs as leaders in all aspects of health care innovation.

XII. CMMI Must Ensure that Each ACO's "Savings" Reflect Real Quality and Efficiency Gains

In these comments, we have repeatedly emphasized that the incentive to reduce costs inherent in a risk-based arrangement can have negative consequences with regard to, for example, decisions about the care beneficiaries should receive and their access to new technologies. There also is a risk that the need to show reduced costs as compared to a benchmark may lead an ACO to manipulate its expenditures in a performance year so they are not included among those used for purposes of the comparison. CMMI must therefore take steps to ensure that it is not rewarding ACOs that generate "savings" only through such manipulations. CMMI has several options in this regard:

- **CMMI Should Require ACOs to Report on How Savings Were Generated:** As you are aware, Pioneer ACOs must report certain information to CMMI as part of the demonstration program. BIO thinks that an important aspect of such reporting is an understanding of the basis on which an ACO's savings were generated. That is, along with the other required information, ACOs should be required to provide, with specificity, information regarding how they generated shared savings through a qualitative narrative of the steps they have taken that they expected to produce savings. Such a requirement will hold the ACOs publicly accountable and help ensure that they are not motivated to seek "savings" by engaging in gaming or other inappropriate cost-shifting. At the same time, CMMI will receive the actual performance data of each ACO and will be able to perform its own quantitative analysis of where the ACO has achieved savings relative to its baseline. Public reporting of both of these statements will allow for CMMI and the ACOs to identify and share in best practices—one of the aims of the Pioneer ACO demonstration—while also holding ACOs accountable for producing savings through quality-driven changes.
- **CMMI Should Proactively Monitor ACOs to Identify Changes in Coding Patterns:** Requiring ACOs to report on shared savings is a necessary, but not sufficient, protection. As is the case with ensuring that beneficiaries have access to new technologies, CMMI has a responsibility to ensure that ACOs are not implementing practices that create the appearance of savings without actually engaging in activities designed to improve the quality and efficiency of the services they deliver. Given the flexibility ACOs have in developing their service delivery models, it is imperative that CMMI fully exercise its oversight authority to ensure that the plans and processes outlined in the ACOs' applications are being implemented and used to help the ACO achieve its savings. BIO urges CMMI to use the data available to it to actively monitor ACOs to identify abnormal shifts in coding or service utilization that may be indicative of an attempt by the ACO to inappropriately achieve savings. ACOs that are identified as outliers should be subject to closer scrutiny and placed under a corrective action plan.

XIII. Conclusion

BIO appreciates the opportunity to comment on the RFI for new ACO models. We look forward to continuing to work with CMMI to address these critical issues in the future. Please feel free to contact me at (202) 962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/

Laurel L. Todd
Managing Director
Reimbursement and Health Policy

BlueCross BlueShield Association

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To: Center for Medicare and Medicaid Innovation

Subject: BCBSA Comments – Request for Information: Evolution of Accountable Care Organization Initiatives at CMS

Date: March 1, 2014

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to respond to CMMI's Request for Information (RFI) regarding the Evolution of Accountable Care Organization (ACO) Initiatives at CMS. We are submitting these comments in response to your Notice published on December 20, 2013.

BCBSA is a national federation of 37 independent, community-based, and locally operated Blue Cross and Blue Shield companies ("Plans") that collectively provide healthcare coverage to approximately 100 million – one in three – Americans. Furthermore, the majority of Plans contract with CMS and sponsor MA or Part D Plans in their markets today. We are pleased to serve several million Medicare beneficiaries under these two important programs.

Our comments are informed by BCBSA's and Plans' extensive experience in Medicare Advantage and commercial ACO programs that support the transition from fee-for-service towards a quality and outcomes-based payment structure.

What follows are our detailed comments to a selection of the RFI questions.

SECTION I: Additional Applicants to the Pioneer ACO Model

A. Feedback on Current Model Design Parameters

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

We support CMS's desire to increase the breadth of the Pioneer ACO program, and its ongoing mission to drive ACOs with a strong PCP foundation to be better care managers with increased accountability for cost and quality outcomes. That goal is consistent with the Blue system approach to contracting with ACOs with a strong PCP foundation. Furthermore we commend CMS for exploring the possibility of a form of increased financial risk for participating ACOs. Plans' experience shows that, by itself, a payment system incorporating only shared savings may indeed yield some improvements in cost and quality, but it cannot begin to have the power to reshape practice patterns as effectively as a system that also puts providers at risk for losses.

CMS should explore ways to offer those organizations interested in ACO involvement more flexibility on the measure-based requirements. This approach may facilitate and increase the

level of interest toward applying for the Pioneer program. Without this flexibility, it may severely limit Pioneer ACO participation.

A key question for CMS is whether the intended goal of the Pioneer ACO program is to increase integration of services and enhanced coordination of care across settings, or to create a program that can be chosen by beneficiaries alongside Original Medicare and Medicare Advantage. If the latter, ensuring that the appropriate consumer protections are in place and that there is a level playing field among Medicare options for beneficiaries is essential.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

Those organizations with potential to offer integrated delivery of care should be encouraged to join, though incentivized by an ACO framework that allows them to realize meaningful achievements quickly, such as within the first year of participation. To provide integrated care, ACOs should have networks with adequate breadth and inclusion of specialists and other providers. One challenge to integration in the ACO organization is a lack of interoperability between EHR and lab systems and medical devices.

Offering such organizations flexibility on measure-based requirements might allow them to achieve meaningful milestones and realize their highest potential, while at the same time broadening and strengthening their level of integration.

B. Population Based Payments

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

BCBSA supports the proposed direction of CMS to establish clear requirements for financial reserves, but we feel that demonstrating a specified level of savings in previous years and financial solvency need to be mutually exclusive events. The driving force behind beneficiaries enrolling in a health plan is their desire for security regarding future health care expenses as well as obtaining their needed health care services. Financial standards and reserves are the primary mechanisms by which states assure beneficiaries that a health plan will be capable of paying for its enrollees' health care covered services currently and in the future. In today's competitive and dynamic health care market, such standards are necessary to assure that health plans (or ACOs) have a financial cushion to protect against the implications of aggressively underpricing products to jump-starts sales, loss of market share, unanticipated increases in utilization, or the enrollment of particularly high-risk individuals.

In addition, the unique complexities of rural health care delivery systems make financial standards even more critical for rural ACOs than for those in urban areas. Rural residents frequently travel outside of their local communities for health care services, which may include emergency or tertiary care. A higher rate of out-of-area services may severely constrain the ability of the ACO to manage the continuum of care – a Medicare Advantage plan's most important cost control tool. As a result, rural ACOs could face a more volatile cost structure than those in urban or suburban areas. The challenges of rural health care suggest that full-risk ACOs may have difficulty attracting enough enrollees to spread risk and to cover fixed

administrative costs. A small population base would limit the potential savings to be earned by the ACO even if costs are controlled – yet the ACO would remain at risk for substantial loss stemming from even a few beneficiaries with complex or costly illnesses. In a rural area where the loss of even one provider causes serious problems, the financial stability of an ACO is a great concern. CMS must ensure that the standards developed for Medicare ACOs reflect the unique characteristics of health care delivery in rural areas, especially providing for adequate financial safeguards

Requiring an ACO to meet financial reserve requirements protects beneficiaries in the unfortunate circumstance where the ACO is unable to meet patient care costs and lack a liquid (cash equivalent) financial cushion. While ACOs may have other means for demonstrating assets – such as investments in land, buildings or equipment – these cannot be readily converted into the cash needed to remain financially solvent. Therefore, clear requirements for financial reserves are necessary.

Section II: Evolution of the ACO Model

A. Transition to greater insurance risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

We do not believe CMS should offer ACOs capitation with insurance risk similar to Medicare Advantage (MA) organizations; in other words, CMS should not consider transitioning ACOs to full insurance risk where they receive a pre-determined monthly fee per enrolled beneficiary for all Medicare A and B services (at a minimum) and, therefore, would assume not only high clinical risks (which relates to how much a particular medical event will cost) but high population risks (which relates to the uncertainty of how many medical events there may be for a given population). A separate program transitioning ACOs to full insurance risk will create a parallel program that unnecessarily duplicates Medicare's current full insurance risk program, Medicare Advantage, causing confusion for beneficiaries and unnecessary administrative and cost complications for the Medicare program. If CMO wishes ACOs to assume full insurance risk, then ACOs should participate in MA.

To promote competition and ensure beneficiaries are fully protected, any entities in Medicare that assume full insurance risk should operate under the same rules to ensure a level playing field. A level playing field will protect beneficiaries and prevent adverse selection among different types or risk-bearing entities. If ACOs that assume full insurance risk are not subject to the same rules and standards as are applicable to MA organizations, they might gain competitive advantages that would hinder competition and result in adverse selection, both of which would cause costs to increase.

Thus, if ACOs are to assume full insurance risk, they must be state-licensed and also met all state solvency requirements – the same standards that apply to MA organization today. If a level playing field applies to all entities assuming full insurance risk, whether an MA organization or an ACO, then logic dictates that all entities subject to the same rules participate in the same program – otherwise, by setting up "separate but equal" programs, CMS will needlessly confuse beneficiaries and create duplicate levels of regulation.

In addition, setting up a separate program for ACOs that assume full insurance risk will raise thorny issues for beneficiaries with Medicare supplemental coverage – for example, will beneficiaries still be able to use their Medigap coverage when receiving services from ACOs that assume full insurance risk? Will the capitated rate be risk-adjusted, and will beneficiaries still have traditional cost-sharing amounts (e.g., 80% for a primary care visit)? Underlying all of these considerations is the fact that beneficiaries that choose to enroll in an ACO need the protection of licensure rules (e.g., solvency, grievance procedures, etc.) to assure access to continuous quality care – now and in the future.

As nothing in current law prevents an ACO from assuming full insurance risk by participating in the MA program, ACOs that assume full insurance risk on a level playing field should, therefore, participate in the MA program.

As explained further below, we believe the focus of the Pioneer ACO program should remain on achieving deeper, broader, and sustainable integration within an ACO, which already entails assuming a high degree of collaborative risk. There are creative ways that ACOs can assume greater clinical/financial risks without assuming full insurance risk.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries).

The answer is tautologous: ACOs at full insurance risk should be responsible for the same risks that apply to MA organizations, as they should be participating as MA organizations.

3. Are there services that should be carved out of ACO capitation? Why?

If ACOs receive capitation with insurance risk, they should perforce be subject to MA rules that care out services related to ESRD, hospice, and all Medicare excluded services.

Though not mentioned explicitly in the RFI, CMS might wish to consider partial capitation arrangements that limit ACOs' risks to a subset of services, such as a monthly fee for per beneficiary for primary care treatment and coordination services provided to a defined population of beneficiaries. An ideal way to test such arrangements would be through the MA program, where ACOs would partner with MA organizations to provide the contracted services. Indeed, as discussed more fully below, increasing partnerships between MA organizations and ACOs would be the most straightforward way of offering ACOs payment arrangements with multiple accountability components.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

The type of agreements for ACOs that take on full insurance risk will necessarily vary by the structure of the ACO to reach a level playing field with other MA organizations.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would not be appropriate for ACOs assuming full insurance risk?

If ACOs assume full insurance risk, the demands of a level playing field dictate that all regulatory and compliance elements in MA would be appropriate for ACOs; or, as we indicated in Question 1, ACOs that assume full insurance risk should participate in MA as a Medicare Advantage Organization. ACOs should be held to the same quality, regulatory and capital reserve standards as any other MA organization.

For all intents and purposes, ACOs assuming full insurance risk would be insurers, and a full-insurance-risk entity entails sound business planning, governance, risk management, and capital resources. A level playing field will insulate beneficiaries from the ailing financial health of an ACO organization, ensuring that beneficiaries are offered secure and reliable health-care choices and that public investment is optimized and protected.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

We assume that the premise underlying this question is that the ACOs in question are transitioning to full insurance risk, hence the need to meet state licensure requirements. If ACOs face challenges in meeting state licensure and solvency requirements for risk-bearing entities, the answer is not to create an unlevel playing field by providing waivers to current regulations or fraud and abuse laws – the onus should be on ACOs to compete against other MA organizations on a level playing field. Anything less would strip away important protections and put beneficiaries at great risk. The Medicare program is not the place to experiment with new insurance-bearing entities: there should be no broad waivers, exemptions, or safe harbors that would undermine beneficiaries' protections and cause level playing field issues.

Waiving otherwise applicable standards will create a substantial risk that new, inexperienced, and potentially undercapitalized organizations could fail and result in problems for CMS, beneficiaries, stakeholder organizations, and the ACO's invested providers. By participating in the MA program, ACOs that assume full insurance risk will meet federal standards for Medicare Advantage and state licensing and solvency standards. This provides a national "floor" for consumer protection, and by holding all entities assuming full insurance risk to the same standards, help prevent unnecessary and unacceptable risks for beneficiaries as well as the Medicare program itself.

Furthermore, we would underscore the risks for beneficiaries of considering any major changes to the anti-trust, anti-kickback, and patient referral laws and regulations to help ACOs take on full insurance risk. The "clinical integration" concept as it has evolved in guidance from the FTC and Department of Justice – which provide a consistent, legal analytic framework – would allow solo and small group practices to move forward with ACO development: "A comparison of ACO characteristics and those used by the FTC to determine whether the goal of clinical integration has been met …shows a high degree of concordance." Broad exemptions would, however, create the significant risk of patient harm by (1) undermining the protections offered by such laws against arrangements that result in inappropriate and unnecessary treatment; and (2) spurring provider consolidation that creates cost-driving market power.

BCBSA supports public policies that promote fair and vigorous competition because we believe this will expand the availability of affordable health care for all Medicare beneficiaries. A healthy, competitive marketplace will best meet beneficiary demands for access to high quality

care, and ACOs that meet all of the standards and protections required of other risk-bearing organizations are welcome to be part of the Medicare Advantage program.

Any waivers or exemption from licensing standards for ACOs would mean beneficiaries receiving care in ACOs would have *separate and unequal* protections from their neighbors who are enrolled in traditional Medicare or Medicare Advantage plans.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

Many Medicare Advantage plans are sponsored by an existing licensed insurance organization. Medicare Advantage plans are at full-risk for all Medicare Part A and B benefits and go through an extensive bidding process and must be state-licensed entities prior to contracting with CMS. Many MAO organizations have commercial lines of business and have experience in administrative functions that are required in both lines of business. In order words, most MA plans when they come to market already have commercial experience that allows them to transfer such capabilities to their MA line of business, e.g., call centers, claim processing, appeals processes, compliance plans, etc.

ACOs that wish to take on full risk will need to develop the same complex set of skills and competencies required for managing insurance risk. This may be a challenge since provider groups generally have less experience in the financing of health care than Medicare Advantage organizations, which specialize in the financial risk management that encompasses improving condition management and health outcomes of members. However, if ACOs assuming full insurance risk are not capable of managing the additional burden of greater financial risk, then the health and welfare of beneficiaries and the financial soundness of the Medicare program would be put at great risk.

As with any new entrant to MA today, ACOs entering the MA program should be thoroughly vetted by CMS to ensure that they have sufficient experience to protect beneficiaries. For example, CMS recently proposed that one full year of benefit experience be required for Part D plan sponsorship. There are many other examples of protections for beneficiaries, such as the proposed requirements for business continuity and the technical safeguards in place for information systems that should equally apply to an ACO attempting to assume full insurance risk. At the same time, to the extent that CMS offers flexibility for new entrants – for example, in giving entrants time to report the full set of quality measures – ACOs that wish to assume full insurance risk will benefit from this flexibility.

Given the challenges to managing full insurance risks, ACOs might better focus on working with MA organizations to implement payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). There is no reason, for example, why an ACO cannot be part of a MA organization's network as a preferred provider in a value-based benefit design, similar to models being carried out in the commercial sector. On the other hand, we see no reason why an existing ACO can't also be a part of an existing MAOs network and be incorporated as "preferred partners" in a value-based MA plan design in an MA option, similar to models being tested in the commercial sector.

B. Integrating accountability for Medicare Part D Expenditures

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

All Part D sponsors have to meet a full list of CMS requirements, including state licensing and solvency requirements. In MA today about 99% of all MA organizations contract with an existing PBM to be able to deliver Part D benefits and services. So, if ACOs were to accept insurance risk as Part D sponsors the ACO would have to create a corporate structure and then team with a PBM and be at risk for all Part D benefits and requirements – which would essentially make them another Part D sponsor, not different than any other in the market today.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

Since there are currently some ACOs that receive Part D data directly from CMS for their attributed patients, it would seem unnecessary for ACOs to have direct relationships with Part D sponsors. Since patients in an ACO likely will be a part of several Part D plans (no single Part D plan will likely serve all patients in the ACO), it would be most practical for CMS to maintain the contracting and business arrangements with Part D sponsors, while sharing the requisite data with ACOs.

C. Integrating accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

While we do feel that it is directionally correct to explore this feasibility, it may be premature to do so at this time without a national dual-eligible policy. Medicaid-Medicare FFS dual eligible beneficiaries and stand-alone Medicaid FFS beneficiaries should not be included in the fully capitated model, due to the regulatory complexity of designing a national program that can flex to individual state regulations, and given the marked differences in the Medicaid vs. Medicare populations.

E. Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

BCBSA acknowledges the challenge of involving private payers to the extent possible in the Medicare ACO program. However, the concept of private payers “adopting ACO contracts” requires further clarification and we would benefit from more specific details as to what that might entail. Is the intent for CMS to encourage other payers to leverage the proposed CMS Pioneer ACO payment model?

We believe that CMS policy and rulemaking should leverage the experiences of private payers as much as possible. Additionally, CMS should consider collecting the experiences of Pioneer ACOs and compare these to innovative delivery models these same ACOs may have joined in

the private sector. By examining these findings, CMS may obtain valuable feedback that would aid in the design of a precise and possibly more practical approach for achieving multi-payer alignment.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

As stated previously, CMS should explore ways to offer those organizations interested in Pioneer ACO involvement more flexibility on the program requirements, particularly the set of measure-based requirements. Providers may feel burdened by the complexity of measure-based compliance. A large number of measures, as opposed to a select few, can be overwhelming and challenging to aspirations for results-driven management.

Private health plans have forged successful delivery models through an innovative framework focused on a few key goals that an organization accomplishes sequentially. We believe it is critically important to the success of the ACO concept – in both the public and private sectors – that Medicare aligns its policies and procedures with, and provides support for private payers' initiatives with ACOs.

We recommend that CMS (1) give preference to ACOs that have contracts with private payers that include financial accountability and quality performance incentives; and (2) avoid requirements that could have a chilling effect on the willingness of private payers to invest in and partner with ACOs.

To minimize administrative burden, CMS should combine a core set of high-priority, mandatory measures with a menu of others on which ACOs would draw would be administratively more feasible and less of an impediment to participation by ACOs. Such a core/menu approach should be consistent with measured being utilized in the private sector currently for similar ACO initiatives. CMS should evaluate the benefit of giving ACOs flexibility in determining the measures, or the weights thereof, applicable to their organization, which would allow the ACO to align with private payers.

Among other benefits, this approach would allow ACOs to customize their measure selections, recognizing that not all measures will apply equally to all ACO configurations, and that flexibility will attract a greater number of program participants. Also, it would provide a broader array of measures from which to select, increasing the likelihood of the ACO measure set serving as a core set on which to draw in multi- and private-payer payment reform initiatives, as CMS envisions. Over time, CMS could phase in a full set of measures as mandatory.

Alignment could facilitate quicker development of sustainable quality practices, thereby allowing an organization to subsequently shift its focus, in a sequential manner, to new measures and then allocate the resources and attention necessary for a subsequent success.

Finally, CMS could evaluate the existing set of Pioneer ACO measures through the lens of a value-stream analysis, which could yield findings that would allow for a prudent redesign of the measure set and methodology, one that could potentially reduce the number of measures that ACOs are challenged to succeed on.

BROWN & TOLAND PHYSICIANS

Response to Request for Information (RFI): Evolution of ACO Initiatives

at the Centers for Medicare & Medicaid Services (CMS)

March 1, 2014

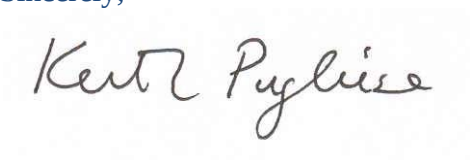
February 28, 2014:

Dear CMMI:

Thank you for the opportunity to provide CMS input on policy considerations for the Pioneer ACO program.

Due to system issues with the RFI portal, Brown &Toland Physicians submits its feedback within this document (pasting in the html survey and response below), as set for below.

Sincerely,



Keith Pugliese
VP, Accountable Care & Public Policy

- Please select the option that best describes you.
  - ☐ Part of a Medicare ACO
  - ☐ Part of a Commercial ACO
  - ◉ Part of both a Medicare ACO and a Commercial ACO
  - ☐ Not part of a Medicare ACO or a Commercial ACO

- **SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters**

  A. The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes based contracting. The Model is now entering its third performance year with 23 organizations. In addition to increasingly aggressive risk arrangements, CMS offers eligible Pioneer ACOs the opportunity to transition from fee-for-service (FFS) payments to monthly population-based payments to give these organizations more revenue flexibility in determining how to best motivate providers to improve quality of care and reduce costs for their patient populations. As more and more health care organizations begin to hone their skills in care coordination and engage in outcomes-based contracting, CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks

input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

- 1. Would additional health care organizations be interested in applying to the Pioneer ACO Model?

  ☉ Yes ○ No
- 1A. Why or why not?

Response: Yes, if risk-adjustment based on HCC coding were incorporated (as is applied in the Medicare Advantage program), and if pre-payment models such as capitation (for either Part B or both Part A and B services, in place of the program's current baseline/benchmark shared-risk methodologies) were utilized.

- 2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?

  ○ Limit the number of selected organizations

  ☉ Accept all organizations that meet the qualifying criteria

- 2A. What are the advantages and/or disadvantages of either approach?

Response: Accepting all eligible applicants would give urgency for CMS to find a viable business model for Medicare ACO, including the need for Medicare payment reform, in regards to the Medicare Fee Schedule and prospective payment systems, as well as in regards to replacing the baseline/benchmark shared-risk methodology with comprehensive pre-payment, population-based methodologies, such as capitation (e.g., 100% Part B or 100% Part A and Part B per beneficiary per month pre-payment for ACO services within ACO service area). Treating the Pioneer ACO program as a demonstration viewed largely through an academic lens has contributed to friction for participants who carry downside risk, such as when CMS changes to methodologies (particularly calculated financial methodologies) are developed or implemented piecemeal, without necessarily understanding business impact to ACOs. Also, CMS should consider implementing a governing board over the program that includes representation from participants, as well as health care industry and market leadership, as opposed to agency-only governance. Additionally, the quality reporting and metric program should be reconsidered to be aligned with the MA program's Star Rating program. Eventually, the industry overall would find it is beneficial to both patients and providers to coalesce disparate programs into one national quality program.

- 3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

Response:

- Data and metrics need to be forthcoming proactively, before a performance year begins, so that ACOs can have the opportunity to implement strategies with its providers for quality

improvement.

- Any program changes, including changes to financial (including any calculated) or quality program methodology, need to be implemented with appropriate prior notice and not be allowed to be effective retroactively.
- In regards to the quality program requirements, metrics need to be realistic and achievable, particularly as viewed in the eyes of physicians and clinicians; for example, no top quartile should contain a threshold metric of 100%. CMS should collaborate with industry leaders such as the integrated Healthcare Association on standardizing quality metrics and reporting across products and programs.
- Claims-based data that CMS sends to ACOs should contain all diagnosis codes and all detail, including unit measures, for header and line detail.
- CMS should validate data – including the structure and the content – before submitting to ACOs.

- B. Population-Based Payments: CMS allows Pioneer ACOs to transition to population - based payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

  Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a 40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

- 1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP?

  ☐ Yes ☒ No

- 1A. Why or why not?

Response:

- A concept of Population-Based Payment (PBP) as pre-payment of potential shared savings that could be recouped back by CMS is not the form of pre-payment that would be viable or feasible for ACOs. PBP should compensate ACOs for furnishing services not currently paid for under Medicare FFS, and to invest in care coordination infrastructure – that is, an ACO investment that is not compensated from a Medicare fee schedule, an investment that is necessary regardless if whether an ACO achieves savings. PBP should not be recoupable.
- Additionally, prepayment needs to be similar to capitation, similar to payment issued by CMS to MA plans, without having a plan in the middle, that is, CMS should capitates ACOs directly for their aligned population, either 100% for Part B services rendered or 100% both Part A and B services, rendered to aligned beneficiaries by the ACO network of providers, within the ACO's service area, so as not interfere with provider cash flow. If the ACO would receive, e.g., full prepayment for Part B or Part A and Part B services, then the ACO can downstream payment to providers per contract arrangement (for example, on a contractual FFS schedule, or case rate, or sub-capitation).

- 2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?

  ☐ Yes ☒ No

- 2A. Why or why not?

Response: PBP should compensate ACOs for furnishing services not currently paid for under Medicare FFS, and to invest in care coordination infrastructure. Additionally/separately, Part A and/or B services should be prepaid via capitation to an ACO, in place of Medicare FFS reimbursement for the provision of services to beneficiaries, including DME services.

- 3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves?

  ☐ Yes ☒ No

- 3A. Why or why not?

Response: ACOs should be responsible for managing their risk, while meeting certain financial solvency criteria, as required by state regulation. Additionally, PBP should reimburse ACOs for their investment in care coordination infrastructure, regardless of whether shared savings are achieved.

- 4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

  ☒ Yes ☐ No

- 4A. Why or why not?

Response: PBP compensates ACOs for to invest in care coordination infrastructure, and so should be separate from shared savings/losses arrangements. PBP should not be retractable, even if an ACO does not achieve savings or incurs losses for the Medicare Trust Fund.

- **Section II: Evolution of the ACO Model**
  The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:
  • Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;
  • Give providers more tools and resources to improve care outcomes and efficiency; and
  • Continue to preserve beneficiary freedom of choice in FFS Medicare.

  CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

- A. Transition to greater insurance risk – ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues.

- 1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations?
  ☉ Yes ○ No

- 1A. What are the potential benefits and risks to the Medicare program and beneficiaries?

Response:
- Benefits: Managing financial risk aligns an organization with care coordination, which benefits patients as well as the Medicare Trust Fund.
- Risks: ACOs need to the experience/expertise maturely manage financial risk, including "Incurred but not reported" (IBNR) projections and meeting state solvency requirements.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

Response: CMS should offer flexible options, because different ACO models may be drawn to

different arrangements: Part A only; Part B only; Parts A and B; Parts A and B and duals.

3. Are there services that should be carved out of ACO capitation? Why?

Response: CMS should offer flexible options, and CMS should draw up a template Division of Financial Responsibility (DoFR) template that allows for negotiation as to whether an ACO would take risk for Parts A and/or B, and, also allow ACOs to negotiate carving out certain services, based on ACO appetite and capacity/capability for taking on risk for certain services.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

Response: ACOs should be allowed to take risk only for its network providers' rendered services; out-of-network (OON) and out-of-area (OOA) services should be the financial responsibility of CMS (unless one ACO's OON or OOA services fall within another ACO's network or service area).

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk?

What regulatory and compliance elements in Medicare Advantage would NOT be appropriate for ACOs assuming full insurance risk?

Response: Key Elements to Adopt:

- HCC-based risk-adjustment program, which would influence prepayment to ACOs based on chronic severity scores per beneficiary, and which would require ACOs to submit encounter data to CMS (as MA plans do).

- Allow ACOs to share beneficiary data for ACO aligned beneficiaries in accordance with HIPAA but without additional restrictions such as the data sharing opt-out allowance used in the Pioneer ACO program. MA plans do not have such a restriction.

- Use the same quality reporting program as is used for the MA star rating program.

- Additionally: ACOs should be allowed to perform prospective utilization review, including the issuance of referrals and authorizations for certain requested services.

- Allow ACOs to enjoy SNF waivers without additional administrative burden (as included by the current ACO SNF waiver), as enjoyed by MA plans.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities?

What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

Response: CMS should require that ACOs meet any state regulatory or licensure requirements within a state in which it operates/provides services. Requirements should include financial solvency standards, as determined by each state.

Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services.

7. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

Response: ACOs who have experience in managing risk likely have infrastructure, including: financial risk management systems and processes (IBNR methodologies, for example, as well as medical cost tracking and containment methodologies); the ability to process claims and encounters, as well as submit encounters to CMS (as MA plans do); and the ability to track referrals and support medical determination review for requests for authorization for certain services.

The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking.

8. What are approaches for setting appropriate capitation rates?

Response: CMS can create a risk corridor -- a floor and a ceiling for rates (adjustments based on age, sex, HCC profile, geography). CMS may want to consider modeling capitation rates on how CMS determines rates for MA. Rates should also take into account whether an ACO would contract for only Part A risk, or Parts A and B risk, or just Part B risk.

Rates in risk corridors can take into account geographies, but CMS may want to consider setting budget targets for certain grouping of services, so that the Medicare Trust Fund can be managed. In other words, set a national budget, and then downstream those budgets for each Part, A, B, and D. ACOs who take risk wile b challenged to manage the prepayment of services that fall within the budgeted rate amounts. If the ACO fails to do so, then the ACO is at risk for allowing its medical expenditure to outpace its top line revenue. Financial guarantees or state financial solvency requirements can ensure that ACOs meet certain financial thresholds in order to operate as ACOs under these risk arrangements. CMS would need to audit ACOs for ensuring that medically necessary services are rendered in a timely manner (and there is no withholding of medically necessary care).

8A. What are the advantages and disadvantages of using national expenditure growth trends?
Response: In full risk capitated arrangements, national growth trends need not be incorporated in determining rates. As stated above, consider using the approach of pre-budgeted amounts divvied out in capitation to ACOs. Using national expenditure growth trends do not afford the ACOs the prospective ability to manage financial risk.

8B. What about for using a local reference expenditure growth trend instead?

Response: In full risk capitated arrangements, local growth trends need not be incorporated in determining rates. As stated above, consider using the approach of pre-budgeted amounts divvied out in capitation to ACOs. Using national expenditure growth trends do not afford the ACOs the prospective ability to manage financial risk.

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

Response: HCC risk adjustment appropriately acknowledges an individual's disease profile for predictive modeling analysis to facilitate the determination of whether an ACO needs to provide preventive and interventional care. Pioneer ACO should use the same risk adjustment approach as MA uses.

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes?

Response: Beneficiaries aligned to a Pioneer ACO should not have 20% out of pocket (OOP) costs that they would otherwise experience in traditional Medicare FFS. Instead Part A and Part B OOP costs should mirror MA OOP (for example, copays). Consider Pioneer ACO as a version of MA but without the MA plan in the middle – but with all the incentives afforded to a beneficiary "member" or enrollee of an MA plan. Benefits should be similar to MA HMO benefits -- with no additional premium, but allowing the Pioneer ACO to coordinate care. This way, by mitigating OOP costs to beneficiaries, then beneficiaries would not be inadvertently dis-incented from accessing medically necessary care, which in turn would result in the improvement of clinical and quality outcomes.

10A. How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

Response: Duals should have no OOP whatsoever.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

Response: CMS should require financial solvency reporting and auditing to states. CMS should apply a beneficiary appeals process similar to MA to ensure that a Pioneer ACO is not withholding medically necessary care. And CMS should audit ACO administration as it does of MA plans.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

Response: ACOs would not need to market to beneficiaries, if they are going to be aligned, as they

are not purchasing or actively enrolling. However, ACOs should be allowed to, as providers, promote the Pioneer ACO program to both aligned beneficiaries and, if the attestation alignment is ever allowed by CMS for the Pioneer ACO program, to prospective beneficiaries. CMS should apply a beneficiary appeals process similar to MA to ensure that a Pioneer ACO is not withholding medically necessary care. And CMS should audit ACO administration as it does of MA plans.

- Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries.

  13. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology?

  ☒ Yes ☐ No

- 13A. What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

Response: Beneficiaries who for whatever reason do not want to enroll in an MA plan but want to enjoy the benefits of coordinated care under the Pioneer ACO program should have the option of actively attesting for alignment.

- B. Integrating accountability for Medicare Part D Expenditures – An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

- Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes.

  1. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?

Response: Non-generic drugs -- and especially experimental or high-cost drugs -- require special Pharmacy Benefit Management (PBM) expertise to manage Part D risk. Part D related ACO models need to have integration with ACO medical management for Part A and/or Part B services, including prior or prospective review for adherence to clinical guidelines and ACO-specific formularies. ACOs need to be able to manage drug utilization and cost as is allowed in MA-PD models.

1A. What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

Response: Part D risk should require PBM capabilities and infrastructure at the ACO level, along with a contractual capitated arrangement either between the ACO ad the Part D Plan (PDP) or

between CMS and the PDP.

- 2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?
  ☉ Yes ☐ No

- 2A. Why or why not?

Response: Possibly -- IF the Pioneer ACO program mirrored the MA program, to allow for network lock-in or incentives, as well as referral and authorization prospective review, in the ACO's PBM program.

2B. If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

Response: As stated above, CMS should consider creating budget amounts to drive capitation rates between CMS and ACOs, and also apply that approach to CMS-PDP arrangements, if PDPs contract with ACOs.

- 3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures?
  ☐ Yes ☉ No

- 3A. What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

Response: Clinical Rx data as well as non-PDP Part D data (e.g., Part D data from beneficiary retiree Part D equivalent plan) would be needed, as not all aligned beneficiaries have PDP coverage for Part D. ACOs should be required to demonstrate PBM capabilities.

- C. Integrating accountability for Medicaid Care Outcomes – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

- CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations.

  1. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?
  ☐ Yes ☉ No

- 1A. Why or why not?

Response: Possibly, if an ACO is managing a dual program or a managed care Medicaid plan. But if an ACO is acting as a Medicare ACO only, then Medicaid outcomes should not be applied to that ACO.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? (For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?)

Response: CMS should allow for flexibility as to what type of accountability an ACO can take, based on ACO capabilities and capacity, and on service area needs. If an ACO is managing a dual program or a managed care Medicaid plan, then the ACO should be held accountable for Medicaid outcomes. But if an ACO is acting as a Medicare ACO only, then Medicaid outcomes should not be applied to that ACO.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?

Response: States need to perform its oversight obligations regarding financial requirements for risk-bearing organizations (RBO). State should not make RBO requirements overly burdensome for ACOs, nor necessarily consider ACOs as equivalent too licenses health plans. ACOs do not sell insurance products to purchasers or beneficiaries (in accordance with the definition of ACOs in the Affordable Care Act). States should allow ACOs to fully administer and manage the ACO program similar to how managed care Medicaid programs are administered by managed care Medicaid plans.

3A. What roles should States play in supporting model design and implementation?

Response: States should play the role of financial oversight. In regards to Medicaid, states could partner with CMS and with ACOs to govern and design ACO programs.

3B. Do States have adequate resources to support an ACO initiative in collaboration with CMS?

Response: Likely not. State resources appear overwhelmed by Medicaid program eligibility changes and by state exchanges.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?

Response: ACOs who manage risk and coordinate care for MA or managed care Medicaid already likely have the expertise and infrastructure in place to integrate data for both programs. This is certainly widely true in California among coordinated care physician groups and ACOs.

4A. What are the capabilities of providers in integrating this data with electronic health records?

Response: ACOs typically have data marts or repositories where cost and risk and clinical data can be integrated for more complete care-focused patient profiles for clinical and total-cost-of-care financial management purposes. Additionally, data aggregator and integrator platforms that incorporate clinical data from more than one electronic health records system is beginning to proliferate throughout the industry. And, of course, when the National Health Information Network (NHIN) formalizes across the country, that would greatly facilitate the exchange of patient information for the place of service at the time of care.

4B. What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

Response: The country is developing NHIN and integrator models. Likely within 3-5 years, more and more ACOs will be better positioned to integrate data from community and other non-traditional care providers. In the meantime, some ACOs may have that ability now (as does Brown & Toland Physicians, for example).

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures?
(Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?)

Response: There should be an integrated financial arrangement, not one arrangement with CMS and one with the state. CMS would need to ensure appropriate and timely administration of the duals ACO program. Financial arrangements should also be of a capitated arrangement, as mentioned for Pioneer ACO above.

- D. Other Approaches for Increasing Accountability – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

- In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives.

  2. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?

  ◉ Yes ○ No

- E. Multi-Payer ACOs – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

- 1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

Response: Commit to payment reform, where the Medicare FFS approach move sot capitation, and encourage federal and state agencies to consider putting certain waivers in pace to encourage the development of ACO arrangements in otherwise FFS chassis products.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

Response: Encourage a one, integrated quality program in the nation, for Medicare, Medicaid, and other government programs, in conjunction with commercial quality programs. And consider having quality measures and metrics co-determined with providers and industry leaders such as the Integrated Healthcare Association.

CAMPAIGN FOR
Better Care

March 1, 2014

Patrick Conway, M.D.
Deputy Administrator for Innovation and Quality
Center for Medicare and Medicaid Innovation
Centers for Medicare and Medicaid Services

Re: Request for Information: Evolution of ACO Initiatives at CMS

Dear Dr. Conway:

The Campaign for Better Care (CBC) appreciates the opportunity to comment on the request for information on the evolution of Accountable Care Organization (ACO) initiatives at CMS. The CBC is a broad-based coalition of consumer organizations with a direct stake in improving the health and quality of life for older adults with multiple health conditions and their family caregivers. We are committed to ensuring that new models of care delivery and payment provide the comprehensive, coordinated, patient- and family-centered care patients want and need while helping to drive down costs.

We commend the work CMS is undertaking to move us toward more accountable care. While the Pioneer and Shared Savings programs were an important first step, we believe CMS now has the opportunity to promote new approaches that go beyond payment initiatives to more fundamentally transform the way care is delivered.

We understand that CMS is considering a range of potential new risk arrangements and structures, with the goals of attracting new participants and improving efficiency and accountability. Our comments will respond directly to some of the questions raised in the Request for Information, but will also present more fundamental consumer policy priorities that must be central to any discussion about the evolution of the ACO programs. Most importantly, as CMS considers the evolution of ACOs, partnering with patients and their family caregivers – the end users of care – at every level will be essential to designing a system that is truly accountable for the right care at the right cost.

The CBC has a long-standing commitment to bringing a strong consumer voice to the development and implementation of innovative models of care. Beginning in 2009, we convened a diverse panel of consumer organizations to develop patient- and family-centered principles to guide the development and implementation of the medical home model of care (attached). These principles provide an operational

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definition of what patient-centered care means to patients and families and identify core elements in ensuring whole-person care, coordination and communication, patient support and empowerment, and ready access. We believe that the most successful ACOs will be grounded in comprehensive and well-coordinated primary care – a true patient-centered medical home – and as CMS considers new ACO approaches and designs, these core elements must be a driving force.

Implementing this vision effectively requires partnering with patients and families at every level. This partnership goes beyond just an occasional focus group or an annual patient experience survey – collaborative patient and family engagement is a systematic and routine method for meaningfully involving patients and family caregivers in decisions concerning their care, and at every level – in care design and redesign, in governance, and at the community level.

The following recommendations aim to help CMS develop new ACO programs that leverage these partnerships to achieve quality, comprehensive, patient- and family-centered care. We believe the Comprehensive Primary Care (CPC) Initiative is an excellent model to draw from.

Engaging Patients and Family Caregivers as Partners in Care

The success of an ACO will depend on the extent to which it engages patients and their families as full partners in their own care and supports their participation in decision-making. We urge CMS to ensure the next generation of ACOs support these partnerships. Specifically:

Shared decision-making

Patients and their families value and benefit from decision-making tools that can help them make good decisions about care together with their clinicians. Patients and their families want guidance from their health care providers, but they also want high-quality, complete, unbiased, up-to-date information that enables them to assess all of their treatment options – including the option of watchful waiting, the risks and benefits of the various options, and how the options align with their personal values and preferences. They want to be prepared to discuss these matters with clinicians and reach the decisions that are right for them. Shared decision-making tools and processes can improve the quality of care with preference-sensitive decisions when there is considerable uncertainty or good information with equipoise among options. Shared decision-making may also play a role when there are evidence-practice gaps and an informed patient might align with better evidence contrary to practice patterns (e.g., practices identified in the Choosing Wisely initiative). When available, high-quality decision tools should be used to reduce unwarranted practice variation and better align care with the needs and values of patients themselves.

We commend CMS for supporting shared decision-making in both the Medicare Shared Savings and Pioneer programs. **As CMS considers new ACO approaches, we urge the agency to include even more support for shared decision-making tools and processes, through robust program requirements and quality measures.**

Collaborative self-management

Supporting patients (and family caregivers as appropriate) in managing their health and chronic conditions is a key strategy not only for engaging patients as partners in their care but also improving outcomes and reducing the need for more costly medical care. **We strongly encourage CMS to require support for collaborative self-management in any new ACO approaches.**

We define collaborative patient self-management as follows:

- Patients are supported in building the skills, knowledge, and confidence they need to manage their health and health care, maintain maximum function, overcome barriers, and achieve personal goals;
- Patient self-management is rooted in a collaborative partnership between the patient, family caregiver as appropriate, and provider;
- Patients are supported "where they are" in their capacity for self-management and assisted in increasing that capacity;
- Patient self-management activities are linked to a care plan, developed together with the patient that reflects their wants and needs, is tailored to their life situation, and has realistic achievable goals;
- A support structure ensures patients and family caregivers have the information they need and are continuously supported. This includes ready access to their medical records, evidence-based information provided at the appropriate health literacy level to support their care decisions, a "point person" they can call with questions, a system for follow-up after hospital discharge or other transitions of care, the option of peer support, and connection with community-based resources.

ACOs should be encouraged to use evidence-based approaches when available to engage patients in their care and support self-management. One such approach is the Stanford Chronic Disease Self-Management Program, which is available across the United States.

Care planning

Individualized care plans are a core element of effective care coordination, and we continue to support an emphasis on care planning in ACO requirements. We encourage CMS to think of them as *shared care plans*, which are jointly maintained and updated by patients, family caregivers, and members of their care team. Proactively and explicitly engaging an individual's family and caregivers in the

development of a care plan helps to ensure that the individual's abilities, culture, values, and faith are respected and care instructions and care recommendations are more likely to be understood and followed.

In 2013, the National Partnership for Women & Families released a report detailing consumer priorities for health and care planning. Consumers envision moving beyond the concept of a care plan as a document fixed in time, to a multidimensional, person-centered health and care planning process built on a dynamic, electronic platform. This next generation of care plans in an electronic environment connects individuals, their family and other personal caregivers, paid caregivers (such as home health aides), and health care and social service providers, as appropriate, and provides actionable information to identify and achieve the individual's health and wellness goals. **We encourage CMS to draw upon the Consumer Principles as a resource (see attached).**

Shared care plans go far in helping ACOs meet CMS's strategic objectives for the program, as well as creating efficiencies for providers. **In the next generation of ACO initiatives, ACOs should be required to provide a patient-centered, bi-directional platform for health and care planning. At a minimum, CMS should specifically require ACOs to:**

- **Record caregiver status and roles using DECAF standards (Direct care provision, Emotional support, Care coordination, Advocacy, and Financial) as appropriate;**
- **Document both patient and provider goals; and**
- **Electronically transmit care plans to patients and caregivers across the care team.**

These pieces of information build upon the summary of care record required for demonstrating Meaningful Use of electronic health records, engage patients and their family caregivers in the planning of care, and provide the necessary foundation for a more patient- and family-centered, comprehensive, integrated plan of care. Ideally, care plans should also enable patient access and ability to contribute and correct health information (such as family health history, goals, chosen support individuals and networks, and advance directive content) to help manage their care and well-being.

Engaging Patients and Families in Care Design/Redesign

Patients and families have unique and valuable perspectives to share when it comes to designing or redesigning care delivery. Only by including consumer voices at the table can ACOs successfully design care in a way that truly meets the needs of patients – particularly the most vulnerable patients – and is embraced by consumers.

We urge CMS to include strong requirements and accountability for consumer involvement in ACOs' care design and redesign efforts. Because ACOs may vary widely in structure, there are many potential opportunities to partner with patients and families in design or redesign. These could include:

- Working with consumers patients and families to ensure an ACO's care coordination efforts are meeting patient/family needs;

- Conferring with patients, families, and consumer leaders about cultural and language barriers and strategies to meet the needs of diverse populations;

- Routinely asking patients and families about experience of care and then collaborating with patients, families and consumers to use the feedback to design quality improvement interventions with consumer leaders; and

- Working with patients, families, and consumer leaders to design patient portals that give patients and families real-time access to their medical records and other functionality they identify as valuable (online scheduling, prescription refill requests, etc.).

Program requirements for any new ACO initiative should facilitate robust and meaningful patient, family and consumer engagement in design/redesign.

Engaging Patients and Families in Governance

Consumers must have a real voice in ACO governance and decision-making. As CMS considers the governance structures of new ACO approaches, the agency must move beyond the requirements of the Medicare Shared Savings and Pioneer programs to promote meaningful consumer engagement in ACO governance. We define meaningful consumer engagement on governance boards and bodies to include the following:

- Proportionate representation (i.e., not having only one patient, family caregiver, or consumer representative on an ACOs' governance board);

- Representatives reflect the population served by the ACO;

- Representatives are "true" consumers:
    - Primary interest is the needs and interests of consumers, patients, and families;
    - No direct financial stake in the health care system (for example, a practitioner or plan representative); and

- Representatives are meaningfully involved in decision-making (i.e., everyone—patients, families, consumers, and providers—have an equal seat

at the table and an opportunity to share their perspectives as decisions are made).

Partnering with Community-Based Organizations

Community-based organizations – like Area Agencies on Aging or Disability Resource Centers – are often untapped resources that can help ACOs address gaps and improve the delivery of care, particularly for the most vulnerable populations, including Medicaid beneficiaries. The Shared Savings and Pioneer programs took some important first steps to foster links between ACOs and community resources. **We urge the agency to build on this work and support greater partnerships between ACOs and community groups, in order to:**

- **Facilitate smoother transitions between care settings** by connecting patients – especially those who are most vulnerable – with services and supports (such as respite care for families, Meals on Wheels, home-based care, etc.) as they transition from the hospital or other care setting to their homes;

- **Gain a better understanding of the populations served by the ACO**. Community-based organizations are generally located in the same communities as the populations they serve, and therefore have a unique understanding of the needs of the population, as well as a real stake in finding solutions that meet the needs of the community;

- **Improve communication**. With their connection to both the health care system and beneficiaries, community-based organizations can serve as neutral entities that help to inform and support an ACO's communication with its population;

- **Prevent duplication of services.** In some cases, a lack of communication between ACOs and community-based service providers may lead to duplication of services. Better coordination will help the ACO to use resources more efficiently to achieve quality care for beneficiaries.

- **Disseminate information.** Community-based organizations often have the ability to disseminate information to their constituents in a variety of ways**,** and as a trusted source of information, can be helpful allies to ACOs seeking to raise awareness about a particular condition or issue, or to promote and event; and

- **Connect with reliable and relevant resources and materials.** Community-based organizations can be helpful partners to the ACO in developing and reviewing materials and tools that are relevant and timely for patients and their families before, during, or after a health care-related

episode.

CMS has already undertaken some innovative steps to support better linkages between health care providers and community-based organizations, specifically, the University of Chicago's Community Rx pilot. This project received a Health Care Innovation grant to set up a real-time automated system to link patients with up-to-date information about community-based services and resources. We encourage **CMS to evaluate the progress of this pilot in considering how to support better connections among ACOs and community resources.**

Additional Recommendations

Accountability for Medicaid Populations

We strongly support CMS's interest in transforming care for Medicaid beneficiaries by pursuing innovative care delivery approaches for this population. These beneficiaries – who tend to have more complex health needs and often face greater barriers to care – may have the most to gain from an integrated system that provides more comprehensive, coordinated care. **It is crucial, however, to ensure that any new ACO model for Medicaid beneficiaries be truly accountable for the care that this population will need, and hence CMS requirements must maintain strong consumer protections and ensure ACOs have adequate infrastructure to meet beneficiaries' needs.**

- It is crucial that all ACOs aiming to serve Medicaid beneficiaries and dually eligible beneficiaries be able to manage and coordinate the full spectrum of dual eligibles' needs, and include within their network providers with expertise in managing this population's unique needs;

- CMS should encourage ACOs to provide intensive care management and home-based primary care services, and include home health agencies, assisted living, SNFs/NFs, and other providers of long term services and supports in their networks to maximize coordination of care for dual eligibles; and

- CMS should strive to identify ways to ensure that ACOs meaningfully partner with existing community-based service providers to coordinate and deliver the community-based services that are especially critical for many Medicaid beneficiaries.

We urge CMS to continue to work closely with consumer advocacy organizations as it considers expanding innovative care for this population. These organizations can help the agency ensure that program requirements provide the appropriate protections for beneficiaries, and that information transmitted to beneficiaries meets their needs and addresses common questions (for example, when

beneficiaries are being notified of their provider's participation in an ACO).

Consumer Protections

As CMS considers new ACO approaches, we urge the agency to ensure strong consumer protections are not sacrificed in efforts to innovate and better integrate care. These goals are not mutually exclusive. This is of particular concern for Medicaid and dually eligible beneficiaries, but important for all individuals receiving care through an ACO. These protections include the following:

- **Non-Interruption of Care** – CMS should ensure that beneficiary alignment or affiliation with an ACO does not create interruptions in ongoing care that cause significant hardships for beneficiaries or result in a reduction of needed services;

- **Transparency and Notification** – Regardless of how a new ACO is organized, we believe there must be full transparency of beneficiary alignment/affiliation. Beneficiaries have a right to know about any new financial incentives that may influence provider behavior and the care that is delivered. Beneficiaries also need to fully understand what they can expect from the ACO, including attributes that differentiate it from the fee-for-service model, like care coordination;

- **Notice** – CMS should ensure ACOs include adequate notice protections for beneficiaries that are consistent with existing requirements – specifically, notice of the availability of treatment options, the right to a second opinion, etc.; and

- **Grievance/Complaints Processes** – For any potential new approach, we believe ACOs must have in place a formal procedure for patients to voice grievances regarding treatment or care (such as the regulatory language for both Medicare Part D and Medicare Advantage). CMS should require ACOs to give notice to patients of their rights to file a complaint under the grievance procedures. CMS should also require ACOs to establish a process to track and maintain records on all grievances received and the disposition of each grievance. ACOs should report this information to CMS on a regular basis, and CMS should have a process in place to issue warnings, put an ACO on a corrective action plan, or terminate an ACO's participation.

Quality Measurement

In any new ACO approaches, we urge CMS to ensure a robust focus on quality measurement and improvement, with the goals of improving the quality of care for patients and families, and supporting their ability to make informed health care decisions according to their values and preferences.

Specifically, we urge CMS to:

- Make available quality information that is meaningful, understandable, and accessible to those receiving care;

- Improve the availability of meaningful measures to support informed decision-making by patients and families, and drive toward a patient-centered delivery system that includes improved clinical outcomes; and

- Stratify and report clinical quality measures by disparity variables such as race, ethnicity, language, socioeconomic data, disability status, sexual orientation, and gender identity data.

We strongly urge CMS to prioritize the collection of patient experience and patient-reported outcomes measures. Measuring patient experience is often the only way to evaluate elements of care that patients and family caregivers identify as most important to improving their health outcomes. Gauging a patient's experience of care is especially important for those who have multiple conditions and for whom condition-specific quality measures cannot provide an adequate picture of the total quality of care received. Family caregiver experience data is also particularly helpful in assessing experience of care for those patients with cognitive impairment that prevent them from talking about their own experience, or provide insights into areas patients themselves may be reticent to discuss.

Communicating with Beneficiaries

Effective communication with beneficiaries regarding ACOs and other new delivery models is vitally important to the success of these programs. For example, a letter notifying a beneficiary that they have been attributed to an ACO may include accurate information – but if it is filled with jargon and comes from an unknown source, it is likely to cause confusion and concern.

We urge CMS to think deliberately about communication with beneficiaries regarding any potential new ACO models, and collaborate with consumer organizations and literacy experts as it considers how best to communicate with beneficiaries. We recommend the following best practices:

- **Notification/Communications from Trusted Sources** – Beneficiaries may not understand what an ACO is. But a letter from the beneficiary's doctor explaining how the doctor is now associated with a particular ACO, explaining what the entity is, and how it will enable the doctor to deliver better care will more positively resonate with beneficiaries;

- **Use Simple and Appropriate Language** – Communications must be clear, use simple language (no jargon), and be linguistically and culturally appropriate. (More detailed recommendations regarding cultural and linguistic appropriateness may be found later in these comments);

- **Explain Beneficiary Impact** – Beneficiaries will want to know how a new program will impact them – for example, whether it will affect their out-of-pocket costs, access to treatments, and advantages (e.g., better coordination of care);

- **Avoid Trying to Do Too Many Things in One Letter –** A notification letter should serve a single purpose – to introduce a new proposal or explain a new change to Medicare beneficiaries. Including too many competing issues in a notification letter can be confusing; and

- **Provide a Toll-Free Number for Beneficiaries with Questions –** Regardless of how well-written the notification letter is, many beneficiaries will still have questions. Provide a toll-free number and a service representative equipped to answer questions.

Health Information Technology and Meaningful Use

Health IT is an essential foundation for delivery system and payment reforms. ACOs and other new models of care require the ability not just to share data, but to integrate it across various sources (i.e., doctors, hospitals, laboratories, pharmacies, registries, and patients) and across various types of data (i.e., clinical, claims, and patient-generated data). Health information exchange is fundamental to achieving the improved quality, care coordination, patient-centeredness, and cost reduction goals of ACOs.

The "Meaningful Use" Electronic Health Record (EHR) Incentive Program, and the technical standards deployed through the parallel ONC Certification program, are accelerating the development of necessary standards and services to make care coordination across health systems easy and efficient for both providers and patients. For example, Meaningful Use is producing standardized data elements for critical records and processes of care that are foundational to successful ACO arrangements, including:

- *Summary of Care Record* – The eligible hospital or professional that transitions a patient to another setting of care or refers the patient to another provider of care provides a summary care record for 50 percent of transitions of care or referrals;

- *After Visit Summary* – Clinical summaries are provided for patients following each office visit;

- *View, Download, Transmit* (V/D/T) – Patients have the ability to view online, download, and transmit to third parties their health information, and the criterion specifies the types of information that must be made available;

- *Population Health Dashboard* – Near real-time (vs. retrospective reporting) patient-oriented dashboards displaying lists of patients with specific conditions or filtering by various demographic or clinical variables for use for quality improvement, reduction of disparities, research, or outreach reports;

- *Health Care Event Notification* – Electronic notification of a significant healthcare event (arrival at an Emergency Department, admission to a hospital, discharge from an ED or hospital, or death), in a timely manner to key members of the patient's care team, such as the primary care provider, referring provider or care coordinator, with the patient's consent if required; and

- *Patient Reminders* – Use of clinically relevant information to identify patients who should receive reminders for preventive/follow-up care; reminders sent to these patients per patient preference.

We were disappointed when the requirement for half of eligible primary care providers to be meaningful users was replaced with a less meaningful quality measure in the final rulemaking for the Medicare Shared Savings Program. **With the next generation of ACO initiatives, we encourage CMS to return to a targeted requirement for ACOs to demonstrate a majority of its providers are meaningful EHR users.**

The arc of EHR adoption exceeds what anyone anticipated five years ago when the HITECH Act was passed; Meaningful Use has been more successful than many stakeholders anticipated. As of December 2013, nearly 90 percent of eligible hospitals had received an incentive payment and approximately 60 percent of eligible physicians were successful meaningful users.[1] This infrastructure for health information exchange should be leveraged in the current and future ACO initiatives, as well as other innovative new payment and delivery models. **Given the success of the Meaningful Use program, we strongly urge CMS to require that at least 50 percent of eligible primary care providers and 75**

[1] Registration and Payment data. HIT Policy Committee meeting, February 4, 2014. http://www.healthit.gov/facas/sites/faca/files/HITPC_Feb2014_HITPC.pdf

percent of eligible hospitals be meaningful users of HIT as a core requirement for becoming an ACO.

To improve both care quality and health outcomes, it is absolutely critical that health IT systems facilitate the safe and secure sharing of information, not just between providers, but among patients, families, and other designated caregivers. Giving patients the ability to view, download, and transmit (V/D/T) their own health information was a monumental advancement for consumers in Stage 2 of Meaningful Use. Giving patients the tools to access and manage their own health information electronically is foundational to patient engagement and high quality care. Our comprehensive national survey, conducted by Harris Interactive in 2012, found that patients value this functionality and that it increases trust by adding transparency to the health care system.[2] **At a minimum, ACOs should have standards and processes in place for beneficiaries to electronically access their health information in a way that is aligned with the "View/Download/Transmit" criteria in Meaningful Use** (at least among providers that are eligible for Meaningful Use). Consistent with Stage 2 Meaningful Use, ACOs should be accountable for having at least 5 percent of their patients accessing their health information online.

Furthermore, given the success of the Meaningful Use program, and the role that ACOs should be playing as leaders in coordinating care, ACOs should be held to a higher standard and must lead the way in fostering health information exchange. ACOs should be required to share care summaries electronically at a greater threshold than is currently required in the Meaningful Use program. ACOs should facilitate the provision of electronic communication infrastructure, such as by making the Direct standards and services available to all their participating providers. ACO participants should use the Direct standard, or a compatible service or capability, to transmit Summary of Care records and, eventually, care plans. Stage 2 of Meaningful Use requires a Summary of Care record to be provided for 50 percent of transitions and referrals, and to provide the record electronically for more than 10 percent of transitions and referrals. Stage 2 will facilitate more robust health information exchange, and ACOs should lead the way.

Cultural and Linguistic Appropriateness

To facilitate and enhance patient and family caregiver engagement in care, all patient-facing information and communication platforms should be displayed in plain language (rather than medical jargon), in patients' preferred languages, with links to explanatory, contextual information as needed, and accessible to those with visual, hearing, cognitive, and communication impairments. Using culturally and

[2] "Making IT Meaningful: How Consumers Value and Trust Health IT." www.nationalpartnership.org/hit.

linguistically appropriate information and platforms to tailor information to the unique needs of patients and their caregivers could significantly improve health equity for patients experiencing health disparities, and is also directly aligned with the mission of the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care. The Meaningful Use program—in current criteria for Stage 2 and proposed criteria for Stage 3—has already been developing functionalities to accomplish this critical objective.

Conclusion

We appreciate the opportunity to share consumer perspectives with CMS as you consider the evolution of ACO programs. We look forward to working with you to ensure that ACOs – and all new care models – are designed in ways that truly transforms the way care is delivered to all patients.

Sincerely,

National Partnership for Women & Families
American Association on Health and Disability
American Hospice Foundation
California Pan-Ethnic Health Network
Caregiver Action Network
Caring From A Distance
Community Catalyst
Families USA
Family Caregiver Alliance
Mothers Against Medical Error
National Alliance for Caregiving
National Council on Aging
National Health Law Program
National Women's Health Network
The American Heart Association
The Empowered Patient Coalition
The Well Spouse™ Association

From: Grant, Marie L [mailto:Marie.Grant@carefirst.com]
Sent: Friday, February 28, 2014 5:39 PM
To: CMS PioneerACO
Cc: O'Brien, John M
Subject: Pioneer ACO Model RFI - Response From CareFirst BlueCross BlueShield - Including Official Response As Well as Text Version

Attached is the CareFirst BlueCross BlueShield official response to the Pioneer ACO Model RFI. Below is a text version of the CareFirst response as well (most directly applicable to Section I, Question 3 in the RFI).

____

At the core of the ACO program is the premise that sustained behavioral change within a provider system – toward more cost effective high quality care – can be achieved through properly constructed financial accountability models that are stable over time.

CareFirst is currently engaged in an Innovation Challenge Award testing, among other things, whether that premise is valid. We certainly believe that it is.

We offer the comments below based on the experience we have had over the past three years with over a million commercial lives and, more recently, with 35,000 Medicare fee for service (FFS) beneficiaries who have been incorporated in our model under a common set of public-private financial and programmatic rules - thanks to our CMMI Innovation Challenge Award.

We offer our views below in the form of ten key ideas/observations regarding how ACO models could be enhanced. These ideas are only briefly described, and we would welcome the opportunity to discuss them with you further.

1. **Place more emphasis on a blended fee for service and global capitation model.**

   The focus on population based payment and global capitated approaches – in which a global revenue or cost target is paid to a health care delivery system - must recognize more explicitly than today that there is tremendous underlying importance to the FFS aspects of day to day payment. Indeed, fee based payments are the basis of most data and supporting analyses of the economic value of care patterns. And, they infuse discipline in financial controls, not to mention provide cash flow.

   The drive to build bundled payments and global capitation in ACO models obscures this and creates a false “either/or” choice in which fee for service aspects of payment are uniformly seen as bad/inferior – when, in fact, they are essential.

   The trick is to control the volume inducing tendencies of FFS by use of global budget limits, not the elimination of the desirable aspects of FFS in its ability to secure data discipline or account for the nearly infinite variability in service patterns to individuals. The advent of ICD-10 and the explosion of the valuable data it offers should not be lost.

2. **Stronger connection between global budget targets and individual or small team provider decision-making is essential.**

   Global population-based budget targets assigned to large ACO health care delivery systems must be translated down to individual physician decision makers – particularly

primary care providers. If there is too great a separation of reward from action/results, no positive results are likely to occur. When an entire integrated health system is accountable, but individual providers are not, no one is really accountable and the incentives are too diffuse or remote.

Small teams of primary care providers – incented to produce better cost and quality outcomes for their particular attributed patient population are critical. Such teams need to be rewarded based on the aggregate outcomes they achieve for their particular pool of patients – regardless of how the larger system does. That is to say, to be effective, incentives must be brought down well below the ACO-wide level to work. This should be emphasized more in the designs sought by CMS, such that incentives flow to providers who are actually making key care giving decisions so that they receive direct reward for outcomes behavior change.

3. The emphasis on risk-sharing models is too strong.

The risk sharing requirement in ACO models narrows the range of players available in creating new ACOs or new models.

Indeed, emphasis on risk sharing models induces only the largest players to play since they are the only ones able to take such risks. These are often hospital centric. This induces monopolies or oligopolies in provider systems that get ever larger – often built around academic medical center cores. This could have the impact of incenting health care providers to create even larger systems, which will make health care ever more expensive and discourage the formation of smaller, leaner and more community based models that are not hospital centric.

So, we see the need to place more emphasis on incentive based (upside only) models, to avoid discouraging non-hospital entities (e.g., independent physician groups) from participating in the ACO program.

4. Sharing from the first dollar of savings should be permitted.

While we recognize that savings are shared from the first-dollar if ACOs exceed a Minimum Savings Rate (MSR) and surpass quality thresholds, the existence of a zone of savings beyond which an ACO must pass in order to achieve the first-dollar reward is well intentioned but discourages participation and makes an already difficult challenge that much harder for the health care system.

Since all change in cost outcomes and quality is on the margin - and even small change can be difficult to achieve on a sustained basis – it is best not to create a moat that must be crossed. Any achievement that stabilizes or even slightly reduces cost in the aggregate should be rewarded from the first dollar of savings against a global target.

5. Do not rebase.

The thought that the achievement of savings results in a lower future base undermines the very action that is sought in ACO behavior. It weakens the drive toward better results right from the start.

Instead, we think it is better to emphasize the sustained beating of trend as the reward after a base period is locked down and illness burden and population changes are accounted for. This will be far more motivational and will be more likely to lead to a bending of trend which – over time – gets to be a tougher target to beat. It is best not to make this challenge even harder by periodically taking away savings that are actually achieved – we strongly believe that this does not result in a sustainable model of change.

6. **Substantial supports are needed to reinforce incentives.**

   Care coordination, transition of care services, enhanced monitoring of chronic patients, comprehensive medication review, stronger home based services and a number of other elements are essential to achieving success and these should be identified more sharply as critical elements in ACO models. Without these - properly defined and arranged - sustained results are not achievable even when financial incentives are strong.

   That is, certain supporting elements in an overall ACO program must be present or the whole cannot succeed. Financial accountability alone is not enough. Greater recognition of and emphasis on these supporting elements should be more evident and be required in future ACO models.

7. **All parts (A, B, D) of Medicare must be included in complete and timely data.**

   The separate coverage parts of Medicare must be seen as an integrated whole and the data that CMS supplies to ACOs must reflect this.

   Routine, reliable, and complete data on beneficiaries across all parts of Medicare coverage are key to the success of ACO models. We strongly encourage CMS to prioritize creating a stable, efficient, and reliable operational data service capability across all parts of Medicare, including addressing the lag in reconciled Part D claims and prescription drug event data.

8. **Care coordination services must be paid and accounted for.**

   The cost of care coordination - in multiple forms - is a necessary element in all efforts to obtain better outcomes on cost and quality. Care coordination services are varied and should be defined. They also should be separately tracked and accounted for – and reimbursed – before savings are calculated. This should be a standard feature of ACO designs. A claims basis of payment for these services is probably essential.

9. **Greater emphasis should be placed on physician centric models – particularly primary care centric models.**

   An important key to the success of future ACO models may be their independence from hospital centric influences and decision-making. The most value-laden decisions made by primary care providers regard referrals to specialists. The widest possible choice in this is critical. Overly integrated models restrict this choice.

   That is, in large, hospital centric integrated systems, referral choices can be largely predetermined and become inwardly focused, self-contained loops – often leading to a

narrow, expensive set of choices. Community based models in which primary care providers are more free to refer to a wider range of specialty choices should be emphasized as an alternative.

10. **Greater emphasis on identifying the necessary changes in Medicare coverage and payment rules should be undertaken with a view toward tight integration with provider incentives.**

    In the end, ACO success will depend not just on the financial accountability of providers, but on a modernization of Medicare benefits and Medicare payment rules designed to induce or reward beneficiary behavior toward greater wellness and care coordination.

    An explicit goal of future ACO models should be the demonstration and subsequent development of an integrated model of Medicare benefit plan design and provider incentives. As an example, the waiving of Medicare cost sharing for beneficiaries who comply with their care plans should be considered and an overhaul of home based service coverage rules should be modeled. This not only helps obtain beneficiary compliance, but improves the ACO's chances of success.

    There are innumerable examples of benefit design changes that should be considered. If a new model Medicare benefit plan is not tested in concert with provider incentives in an integrated way, the future pathway to sustained better outcomes will be sub-optimized.

One final overarching thought: The creation of a common model – composed of similar/identical programmatic and financial rules for both the public and private health care financial systems – requires a sensitive eye to private market needs. While we recognize the current Pioneer ACO multi-payer requirement, we are concerned that ultimately, ACOs will be Medicare and Medicare/Medicaid only in their operation. One such common model is precisely what we are demonstrating in our CMMI Innovation Award. Without a common model, provider behavioral change will be thwarted or suboptimized. There are more considerations here than may first be evident.

We appreciate the opportunity you have offered to make these comments. Again, we stand ready to further discuss these thoughts and help CMS consider them. We can relate each of these ideas to the extensive, practical real world experience we have gained. We are prepared to assist you and your team in any way that you may find useful in seeking to advance ideas that are beneficial to the future success of ACO models.

CHCS Center for Health Care Strategies, Inc.

February 28, 2014

Hoangmai Pham, M.D.
Acting Director
Seamless Care Models Group
Center for Medicare and Medicaid Innovation
200 Independence Ave SW #314-G
Washington, DC 20201

Re: CMMI/CMS RFI: "Evolution of ACO Initiatives at CMS"

Dear Mai:

We are writing to submit a response to the CMMI/CMS "Evolution of ACO Initiatives at CMS" Request for Information (RFI). We have also submitted a response on https://cmsgov.wufoo.com/forms/rfi-evolution-of-aco-initiative-at-cms/, but believe that there may be some helpful context to this response that could not be submitted through the online form.

Our response is informed by insights into Medicaid accountable care organizations (ACOs), which CHCS has collected from states participating in its *Advancing Accountable Care Organizations in Medicaid: A Learning Collaborative* initiative. States currently involved in this initiative include: Colorado, Maine, Massachusetts, Minnesota, New York, Oregon, Vermont, and Washington.

State Medicaid agencies are positioning new ACO programs as lead strategies in their efforts to improve quality and reduce costs of health care services. States have taken a variety of approaches to pursue this goal, including adapting broader ACO models, such as the Pioneer ACO and Medicare Shared Savings Program (MSSP), to address the needs of Medicaid populations. While many states face common issues with their Medicaid populations, varying program attributes (such as demographic information, Medicaid eligibility status, and carve-outs) and delivery systems (presence/prevalence of managed care organizations, health homes, patient-centered medical homes, behavioral health organizations) make it necessary for states to tailor ACO solutions to address state-specific needs. This includes determining program design elements such as ACO governance/provider structure, targeted populations, payment methods, quality metrics, and integration of Medicare-Medicaid beneficiaries. Additionally, to successfully adapt the Pioneer ACO model to Medicaid, states must integrate managed care into the approach since 71% of Medicaid beneficiaries are enrolled in managed care. This proportion will continue to grow as more people with disabilities, as well as the new Medicaid expansion population, are included in managed care arrangements. States believe that CMS can provide important guidance, recommendations, and support to help achieve these goals, but that states will ultimately be the primary drivers in determining the most appropriate state-specific strategies.

We hope that you find this response helpful, and look forward to helping CMMI and CMS promote the next generation of ACO models in Medicaid.

Sincerely,

Tricia McGinnis
Director of Delivery System Reform

Stephen A. Somers
President

This response includes direct replies to questions in Sections C, D, and E of the RFI, some of which are broken down into sub-questions. For each question and subquestion, CHCS' responses are bulleted and in italics.

Section C - Integrating Accountability for Medicaid Care Outcomes

As part of the State Innovations Model (SIM), CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

Question 1

CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

- *States are currently pursuing a variety of ACO models that are tailored to their Medicaid populations, existing delivery systems, and programs and capabilities. In order to serve Medicaid beneficiaries, states may choose to require Medicare ACOs to apply to become Medicaid ACOs and meet state-established criteria. If Medicare and Medicaid patients (as well as Medicare-Medicaid beneficiaries) will be served by ACOs, states believe that a standardized set of quality metrics should be used for both payer types to cut down on administrative burdens and align with other CMS initiatives, such as health homes. However, due to different state dynamics and program goals, this may not always be possible.*

Question 2

What populations should CMS prioritize in integrating accountability for Medicaid outcomes?

- *States should be given the latitude to define which Medicaid beneficiaries will be included in ACO programs to best meet their specific policy objectives. When defining beneficiary populations covered by Medicaid ACOs, states are mindful to include populations that will: (1) enable the greatest opportunities for quality improvement and cost savings; (2) align with other programmatic goals and strategies for specific populations; (3) enable the ACO to serve a large enough population to yield statistically reliable changes in cost and quality; and (4) align well with existing capacity of the underlying delivery system to implement these changes. A one-size-fits-all approach to priority populations may hinder uptake in certain states that may otherwise have a strong ACO foundation.*

Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries?

- *State Medicaid agencies have already begun to implement Medicaid ACO programs that are responsible for most Medicaid and CHIP beneficiaries, rather than targeted to specific patient populations. Leading-edge states, such as Minnesota and Oregon, have instituted programs that hold providers and managed care organizations (MCOs) responsible for the outcomes of these beneficiaries. Other states, including Maine and Vermont, recently issued RFPs to providers to establish ACOs to cover a state-defined set of Medicaid beneficiaries. Maine, Minnesota, and Vermont received applications from numerous organizations, including some currently participating in Medicare Shared Savings Program or CMMI Pioneer ACO program. Over time, these efforts may*

be scaled up to cover additional Medicaid and CHIP beneficiaries/populations, including patients eligible for both Medicare and Medicaid.

Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

- *While Medicaid ACOs may eventually be able to assume responsibility for all Medicaid beneficiaries in a specified geographic area, a more incremental approach may be the best strategy for many states to reach this goal of caring a broad range of populations. States support CMS/CMMI's efforts to strive toward this goal through the SIM initiative and other programs, but suggest that state Medicaid agencies be allowed to approach this goal in their own ways, as geographic accountability may be more suited for certain states than others.*

Question 3

What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?

- *Since states know their populations, stakeholders, and health care market environment, states are best positioned to determine the incentives that would foster the development of integrated care systems (including where and when to include upside and downside risk), while also adhering to federal regulations. A standard incentive methodology constructed at the federal level would likely not allow the flexibility that states require to meet state policy objectives and achieve buy-in from providers, payers, and other stakeholders. For example, states have made methodological modifications to the MSSP shared savings/risk model, in ways that vary from state-to-state. CMS should provide ample support and guidance in methodology development, which will lend political credibility for these efforts, but the ultimate decision about how to construct the incentive program should rest at the state level.*

What roles should States play in supporting model design and implementation?

- *Because integrated care programs must work in concert with existing state Medicaid care delivery and payment models, states should take the lead in developing programs and models that create incentives for integrated care systems. States can help foster model design and implementation of ACO initiatives in a number of ways, including: (1) governance structure requirements; (2) provider participation requirements; (3) patient attribution models; (4) quality and outcomes measurements; and (5) guidance on coordination with other delivery system reforms (such as health homes, managed care, and behavioral health organizations)*

- *Where possible, Medicaid and Medicare initiatives should complement one another. For example, if technical assistance programs for a certain topical area are already offered by CMS, states should be informed of this so they can design a program that is not redundant.*

Do States have adequate resources to support an ACO initiative in collaboration with CMS?

- *While some states believe that they have the resources to support an ACO initiative, not all states do. In general, additional federal guidance and resources may help accelerate the implementation of these initiatives by providers and health plans. CMCS can assist and accelerate this process by offering: (1) enhanced FMAP for related state-level development investments in HIT, data, staff resources, and technical assistance, over a defined time period; (2) planning grants similar to those*

available for Medicaid health homes subject to standard FMAP; (3) implementation grants for HIT and EHR access at the provider level; (4) consultation from subject matter experts on HIT and HIE data access and sharing, especially around transitions of care when integrating behavioral health, long-term care, and those recently released from prison; (5) resources for actuarial analyses; (6) technical resources to support integration of ACOs with existing delivery system reforms, such as health homes, PCMHs, and BHOs; and (7) incentives or other encouragement for commercial insurers to participate in demonstrations alongside CMS and states.

- *States also believe that direct technical assistance from CMS is very helpful, especially through the review and approval process. CMS should specify pathways to approval of accountable care and alternative payment models, including through state plan amendments (SPAs) and 1115 waivers. Clear guidance about what is permissible under a SPA and what requires waiver authority would be extremely helpful to states.*

Question 4

What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

- *IT, EHR, and data analytic capabilities vary widely among providers. Despite the advances made by the ONC's Meaningful Use program, access to data and EHR adoption among providers remains spotty, especially in rural areas. Due to these discrepancies, technical assistance to providers is crucial for care delivery transformation and building financial capabilities. States also face barriers when attempting to integrate behavioral health data due to substance abuse information regulations under 42 CFR Part 2.*

- *There are also many barriers that states would need to address if Medicare-Medicaid patients are included. Some states have had difficulty obtaining Medicare data, and those that have access to Medicare data also face a roughly one-month lag for receiving these data, which could inhibit rapid-cycle improvement. Wherever possible, elements of data reports (such as what is analyzed and how it is formatted) should be uniform between Medicare and state Medicaid agencies. States may also benefit from CMS grant support for integration of Medicare, Medicaid, behavioral health, and public health data. To be truly effective, ACOs need real-time access to Medicaid and Medicare data for both physical and behavioral health claims.*

Question 5

What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures?

- *There may not be a single financial arrangement that would be universally appropriate for ACOs. To date, states have pursued a variety of arrangements for Medicaid ACO models, including shared savings, capitation, and global payments. The flexibility to pursue these models is essential for states to gain buy-in for these arrangements given the positions of their stakeholders and varying political environments.*

Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

- *States believe that CMS should offer, but not require, both separate but coordinated and unified shared savings arrangements to give states the option to select the approach that will best fit their existing programs and populations. Both coordinated and unified shared savings approaches would face significant challenges if implemented within state ACO models. While a coordinated approach would allow the flexibility needed to keep payment rates and services separate by program, it would create a large administrative burden on states and ACOs to track both shared savings arrangements. While a unified model would ease the administrative burden, the payment model would need to address how states would attribute and distribute Medicare and Medicaid costs and savings among providers and programs. Additionally, states like Oregon have prospective global budgets already in place that may be hampered by a mandatory shared savings arrangement.*

Section D - Other Approaches for Increasing Accountability

CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

Question 1

A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns.

What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?

- *Such models would need to have a standard set of quality metrics and consistent payment structure to avoid overburdening providers with reporting and accountability requirements. Additionally, since each state's health care market is different due to varied prevalence of managed care, geographic nature (rural vs. urban areas) and other concerns, states are best positioned to determine the model that fits their environment. While states welcome a list of payment and delivery system options that CMS recommends pursuing, it should allow states the flexibility to select which option(s) to pursue.*

What are the most critical design features of a provider-led community ACO model and why?

- *Provider-led community ACO models incorporate many health care providers and institutions, and should have a well-designed corporate structure, a strong data infrastructure, and agreement on how to coordinate care across settings. Since community ACO models are population-based, non-traditional health providers, community resources, social services, and public health should also be involved in the development, and possibly the operation, of the ACO.*

What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area?

- *If ACOs are population-based, quality metrics should reflect broader measures of health – such as behavioral health, social determinants, and overall population health -- in addition to clinical*

outcomes, evidence-based processes, and patient satisfaction measures. States believe that CMS could also consider utilizing these metrics as "alternate" metrics rather than additional ones, because if population health is the goal of the ACO, the focus in metrics will likely shift away from complex medical needs toward more preventive metrics.

Are there models to consider that better integrate community-based services beyond the traditional medical system?

- *Some states have found that health homes, behavioral health organizations (BHOs), and community mental health centers have been effective in integrating community-based services. While early experiences suggest that these could be promising models for integrating community-based services, states need flexibility to experiment with models given that evidence is still emerging.*

Question 2

In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?

- *CMS should allow states to select and design their own accountable care models. This will allow the state to select the optimal approach for their community ACO model. While states would welcome model suggestions from CMS, they should have the flexibility to adapt these models to suit their purposes and populations. Further, CMS should consider allowing organizations to participate in multiple initiatives at once, though oversight would be needed to ensure that the organizations would not be receiving multiple payments for performing the same services.*

More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

- *While states should have the option to pursue ACO models that test comprehensive primary care or episode-based payment, these approaches should not be required. For states that are in the early stages of reform, it might be helpful for CMS to develop some examples of what a layered approach might look like. However, CMS should not require states that are farther along to fit within the confines of these models.*

Section E - Multi-Payer ACOs

CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

Question 1

How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

- *Some states have suggested that CMS could encourage adoption of ACO contracts by other payers in a number of ways. CMS can: (1) produce a contract template that states and payers can use as a*

starting point to begin to formulate their own approaches; (2) communicate promising results from ACO contracts to help make the business case for participation clear to other payers; (3) foster the participation of national payers by encouraging the use of uniform reporting standards across payers or defining objectives of a ACO approach; (4) allow Medicaid agencies and health plans to share in acute care savings for Medicare-Medicaid enrollees; (5) initiate learning collaboratives that convene relevant payers to promote alignment across metrics, data reports, attribution, and other key issues; (6) provide guidance on how states should approach risk-based payment arrangements and the potential for shared losses; and (7) determine an approach that allows innovations from the Pioneer ACO model to be extended to Medicare Advantage contracts.

Question 2

How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

- *CMS can focus quality reporting on the optimal number of targeted measures by encouraging the use of uniform reporting standards and quality metrics across payers. The federal government should not require a uniform set of core metrics. However, if CMS clearly supported states and plans in developing a uniform set of measures that would be relevant across payers and populations, it would be helpful and could ultimately achieve the same result.*

CHCS Center for Health Care Strategies, Inc.

February 28, 2014

Center for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, MD 21244

Re: CMMI/CMS RFI: "Evolution of ACO Initiatives at CMS"

Dear CMS Official:

The Center for Health Care Strategies (CHCS) is writing to submit a response to the CMMI/CMS "Evolution of ACO Initiatives at CMS" Request for Information (RFI). CHCS' response to this RFI draws largely from its experience with broader state Medicare-Medicaid integration efforts. CHCS has worked with states for several years to help them explore and implement emerging options, best practices, and replicable programs for Medicare-Medicaid beneficiaries through various models of integrated care and innovative program design.

States and CMS are currently partnering to test new ways to improve alignment of Medicare and Medicaid financing and delivery to enhance care and reduce costs for dually eligible beneficiaries, such as the Financial Alignment Initiative. CHCS is engaged is several states' initiatives. For example, we operate the Integrated Care Resource Center (ICRC), through which we provide technical assistance to CMS' Medicare-Medicaid Coordination Office (MMCO) and specific states to support their efforts to implement a Financial Alignment Initiative or other integrated care program. CHCS also leads other initiatives that build state capacity to design or implement integrated care programs for Medicare-Medicaid beneficiaries, such as our *Implementing New Systems of Integration for Dual Eligibles* (INSIDE) project with Arkansas, Arizona, California, Colorado, Idaho, Kentucky, Massachusetts, Michigan, Minnesota, New Jersey, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia and Washington. Through these projects, CHCS has helped states consider the major operational, administrative, oversight, quality improvement and financial issues in designing these complex programs for vulnerable populations and effectively implementing integrating care.

We hope that you find this response helpful, and look forward to helping CMMI and CMS promote the next generation of ACO models.

Sincerely,

Michelle Herman Soper
Senior Program Officer
CHCS

Carolyn Ingram
Senior Vice President
CHCS

CHCS Center for Health Care Strategies, Inc.

CHCS Response to CMMI/CMS RFI: ACOs for Medicare-Medicaid Beneficiaries: Select Questions

Section C - Integrating accountability for Medicaid Care Outcomes

As part of the State Innovations Model (SIM), CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

Question 1

CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

Allowing Medicare ACOs to expand their accountability to Medicaid outcomes provides an opportunity to improve care management, coordination and quality of care for Medicare-Medicaid beneficiaries. Many of these activities—such as the Financial Alignment Initiative—involve several thousand beneficiaries in each participating state and use health plans to manage services. Many requirements related to care models and coordination for these programs are highly prescriptive to reflect the scale of the initiatives and ensure state capacity to monitor quality. ACO providers generally have more flexibility in designing, creating standards, and managing care management and coordination activities under current models. Given these differences in care model prescriptiveness, CMS and states will need to work closely on program criteria to achieve the appropriate balance and ensure that policy objectives are met for both beneficiary populations.

Based on our work with states, CMS may want to consider the following factors when determining if ACOs caring for Medicare outcomes should also assume accountability for Medicaid outcomes of Medicare-Medicaid enrollees.

- Presence of Financial Alignment Initiatives. As of March 1, ten states have signed Memoranda of Understanding (MOU) with CMS to pursue Financial Alignment Initiatives: California, Colorado, Illinois, Massachusetts, Minnesota, New York, Ohio, South Carolina, Virginia, and Washington. Both Medicare ACOs and these initiatives are designed to generate Medicare savings through improved quality and care coordination; however, dually eligible beneficiaries can only be attributed to one federal demonstration for Medicare savings calculations and evaluation purposes. CMS should consider if there will be conflicts in assignment of beneficiaries to different initiatives in the same region or the presence of several initiatives might reduce enrollment below the required thresholds or effective population sizes. In addition to attribution issues, it may be difficult to distinguish between what drives clinical and financial outcomes if the same providers serve individuals in both ACOs and Financial Alignment Initiatives.

- Other state activities to promote integrated, managed care. Some states require or will soon require their Medicaid managed care organizations (MCOs) to be qualified Medicare Advantage Dual Eligible Special Needs Plans (D-SNP). This requirement will allow states to encourage Medicare-Medicaid beneficiaries to enroll in aligned products to receive Medicare and Medicaid services from the same organization. Although it is unknown if Medicaid beneficiaries enrolled

in Medicaid MCOs would be allowed to participate in ACO models under discussion, Medicare Advantage D-SNP enrollees may not be attributed to Medicare ACOs.

- Quality metrics for Medicare-Medicaid populations. States participating in the Financial Alignment Initiative will collect data on a combination of "core" measures, many of which reflect services covered by Medicare Parts A and B. However, integrated programs for Medicare-Medicaid beneficiaries include behavioral health services, care coordination, and long-term services and supports (LTSS) that are not covered under Medicare Parts A and B or evaluated by traditional medical care quality metrics. Performance measures for these other services will be included in Financial Alignment Initiative models, but their use is not required by Medicare ACOs and may be challenging to implement in an ACO system. Most of these measures vary across states, reflecting differences in state measurement priorities and LTSS programs. Examples of information some states have determined important to collect for this population include timeliness of clinical and functional assessments; care plan development and community service linkages; overall care coordination; changes in functional status; nursing facility or other institutional admissions and maintenance of community transition; and member-centeredness of care plan.

- Quality measurement administrative burden. As appropriate, CMS could consider using a standardized set of metrics where relevant for both payer types and populations to minimize administrative burden. For example, both Medicare and Medicaid programs collect HEDIS and CAHPS data, and, as noted above, Financial Alignment Initiative models will require reporting on certain core measures. For dually eligible enrollees receiving LTSS, both Medicare and Medicaid use some standardized measures for collecting data on institutional measures of LTSS, such as those reported for nursing facilities in the CMS Nursing Home Compare website. CMS could consider requiring ACOs that care for Medicare-Medicaid beneficiaries to report on nationally recognized measurement sets that are required by both programs in addition to state- and Medicare-Medicaid beneficiary population-specific metrics.

Question 2

What populations should CMS prioritize in integrating accountability for Medicaid outcomes?

If CMS chooses to prioritize populations for integrating Medicaid outcomes into an ACO structure for Medicare-Medicaid beneficiaries, considerations include:

- Existing infrastructure that supports integration. If existing infrastructure in Medicare Shared Savings Program (MSSP) or Pioneer models does not support an appropriate model of care for Medicare-Medicaid beneficiaries, CMS might conduct a cost-benefit analysis of building specific capacity in current programs to expand accountability. Program elements to assess include existing provider access, availability and willingness to operate in a multi-disciplinary care model; state and provider initiatives to integrate or coordinate LTSS and other social supports, behavioral health, and primary/acute care; and other provider resources such as information technology.

- Provider and service mix. If CMS decides to target Medicare-Medicaid beneficiaries with complex needs, CMS should consider expanding Medicare ACO models to include behavioral health, LTSS, and other community service providers. Without including these providers in a shared accountability model, these programs could risk generating more cost-shifting and

inefficiencies between Medicare and Medicaid that these initiatives are attempting to resolve. To increase coordination between programs, Medicare providers would need to develop linkages and intervention strategies between primary care and other acute care providers, hospitals, nursing facilities, and post-acute care settings with LTSS providers and groups such as Community Centered Boards (CCBs), community mental health centers, Area Agencies on Aging (AAAs), and home health providers.

- Size of population for measurement. Targeting sub-populations of Medicare-Medicaid beneficiaries may hinder efforts to establish a statistically significant evaluation population and/or generate meaningful savings from improvements in Medicare service delivery. For example, one decision point with which states and CMS grappled in designing Financial Alignment Initiative models was establishing the size and geographic range of the demonstration population. In addition to potentially reduced state savings, fewer attributed lives may reduce overall financial feasibility to cover administrative costs (e.g., operation of a Medicare claims payment system) and opportunities to integrate LTSS into medical care for individuals.

- Existing service delivery models for Medicare-Medicaid beneficiaries or other high-risk Medicaid beneficiaries. States with Financial Alignment Initiatives will already have those beneficiaries attributed to that model. There could be risk of service duplication in states with robust Medicaid health home or other managed fee-for-service models that provide similar services. Also, CMS should consider whether to include beneficiaries in Medicaid managed care if ACO providers contract with Medicaid MCOs in those states. Lastly, many states are adopting or expanding managed long-term services and supports (MLTSS); by the end of 2014 half of the states are expected to have MLTSS programs. Many of these systems are designed to reduce fragmented acute and primary care, behavioral health, and LTSS; CMS may want to consider if ACO programs should work with these existing programs.

For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65?

General considerations for limiting intervention groups to small sample sizes are discussed above. States should be given the latitude to define which Medicaid beneficiaries will be included in ACO programs to best meet their specific policy objectives. There are advantages and challenges to limiting accountability for Medicare-Medicaid beneficiaries over or under age 65, and decisions may be influenced by the capacity of the underlying delivery system and the outcomes CMS, states, and providers want to achieve. Additional considerations include:

- Medicare-Medicare beneficiaries under 65: The under-65 population is more likely to qualify on the basis of a physical or mental disability, and have a higher prevalence of behavioral health disorders. If states would like to target behavioral health conditions or other high-risk, high-cost Medicaid populations, they might focus on those under age 65.
- Medicare-Medicare beneficiaries over 65: Existing MSSP or Pioneer models may determine it is less burdensome to initially cover Medicare-Medicaid beneficiaries age 65 and older because they will have more similar health characteristics, chronic condition co-morbidities and functional status as Medicare-only beneficiaries and thus may have more similar service needs. People who qualify for dual eligibility over age 65 are more likely to do so because of income qualifications (i.e., they meet Medicaid income eligibility) and receive Medicare because of their age.

Question 3

What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?

States should have a seat at the table with CMS to develop a framework for shared accountability for coordinating and aligning service delivery and financing for Medicare-Medicaid beneficiaries. Although much of the initial savings generated from integrated care programs may accrue to Medicare, states and Medicaid providers should be reimbursed and rewarded for important contributions they can make to these new models of care. States can offer CMS critical input in developing a strategy for achieving seamless access to services; improving care experience; and reduce cost shifting across acute, post-acute and LTSS settings. States and CMS have some experience in working together to develop unified payment approaches for capitated and coordinated shared savings arrangements for managed fee-for-service models under the Financial Alignment Initiative.

States have experience in designing incentives to provide person-centered and lower cost care in the community as appropriate alternatives to institutional settings. For example, many state MLTSS programs have developed payment structures and strategies for using financial incentives to promote use of HCBS and community-based linkages for individuals transitioning out of hospitals or skilled nursing facilities.

What roles should States play in supporting model design and implementation?

States are actively partnering with CMS to set parameters/standards, design program elements, and prepare for Financial Alignment Initiative implementation. Although the program must meet several Medicare administrative requirements, states drove the design of integrated care delivery models, which include acute, primary, behavioral health, and LTSS. Examples of operational and policy program elements that states developed include:

- Care delivery models and related requirements for care management (e.g., care coordination, care team qualifications, and caseload/beneficiary contacts);
- Processes and standards for care transitions across settings, and comprehensive assessments/reassessments;
- Health promotion and wellness activities;
- Rate cells and risk stratification methodologies for individuals receiving behavioral health, Medicaid LTSS in institutions or in the community;
- Processes for assigning beneficiaries to rate categories; and
- Performance metrics that link to financial incentives/quality withholds, promote HCBS over institutional placement, and improve contract monitoring/reporting related to behavioral health, LTSS or other state health quality goals.

States are also skilled at engaging Medicare-Medicaid stakeholders, an essential component pre- and post-implementation of integrated care programs. States have experience in collecting, analyzing and incorporating appropriate feedback from beneficiary, family, provider, and health care entities into program design and implementation strategies, as well as using stakeholder insight to improve current program operations. CMS could consider providing states with a mechanism to gather and incorporate this feedback into any new program for high-need, high-cost populations.

States can help improve model design and implementation of ACO initiatives by incorporating initiatives underway to rebalance LTSS from institutional settings to home- and community-based care. States are

pursuing opportunities made available in the Affordable Care Act (ACA) to expand the availability of HCBS to Medicaid beneficiaries. States are also reviewing Medicaid eligibility processes to ensure that people have the information and services they need to stay in the community, utilizing different federal authorities to better fit the goals of their LTSS programs, and moving to MLTSS programs.

Do States have adequate resources to support an ACO initiative in collaboration with CMS?

States greatly benefit from CMS funding to build infrastructure and capacity to better serve complex populations. CMS has facilitated state investment in developing innovative models and building key program elements such as health information technology (HIT), data, staff and other resources through enhanced FMAP (for a specified period of time and specific activities) and planning grants. Examples of valuable CMS support for states include:

- Medicaid Health Home Option. Section 2703 of the ACA created the Medicaid Health Home State Plan Option that provides a comprehensive system of care coordination for Medicaid individuals with chronic conditions, including eligible Medicare-Medicaid beneficiaries. Health home providers coordinate all primary, acute, behavioral health, and LTSS to treat the "whole-person." There is an increased federal medical assistance percentage (FMAP) of 90 percent for health home services for the first eight fiscal quarters that the health home state plan amendment is in effect. This enhanced FMAP is an important source of support for states to hire staff for care management coordination, purchase HIT infrastructure, and build capacity to deliver other key services.

- State Demonstrations to Integrate Care for Dual Eligible Individuals. As a precursor to the Financial Alignment Initiative, in 2011 CMS awarded 15 states up to $1 million each to develop a new approach to better coordinate care for dual eligible individuals. Under this design grant, California, Colorado, Connecticut, Massachusetts, Michigan, Minnesota, New York, North Carolina, Oklahoma, Oregon, South Carolina, Tennessee, Vermont, Washington and Wisconsin had one year to design an integrated care program structure and implementation plan. Although their models continued to evolve, this grant opportunity provided initial support for the states' design of the capitated or managed fee-for-service financial alignment models later proposed to CMS. Seven of the ten states with signed MOUs received these grants.

Question 4

What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

CHCS has worked with states on integrating and using Medicare FFS and Medicaid FFS data, and this response reflects that perspective. States and CMS are working to improve their capabilities to integrate and use Medicare and Medicaid FFS data. For example, states may now enter into a data use agreement (DUA) with CMS to obtain Parts A, B and D data for Medicare-Medicaid beneficiaries. However, compiling and managing Medicare data—as well as linking Medicare and Medicaid data—are administratively complex undertakings that are new to most states. Challenges with developing this expertise include: (1) creating in-house capabilities to track timeliness, quality and completeness of data sets; and (2) analyzing the data to monitor service use, cost patterns, quality measures and other performance indicators program levels. Also, adjudicated Medicare data have lags that can hinder on-the ground care coordination activities that are essential for dually eligible individuals across each program.

Many "non-traditional" Medicaid providers (e.g., HCBS and community behavioral health providers) do not have access to advanced data systems. As states develop their own internal capacity to collect, analyze, and use integrated Medicare-Medicaid data, they are also working on approaches to assist providers. While many of these activities are at initial phases and state capabilities vary widely, a few states have advanced systems that use linked data for predictive modeling, rate setting, care coordination, and risk stratification. Washington State is an example of state that has had considerable success in integrating data from several state systems to identify Medicaid beneficiaries with complex health needs through a web-based clinical decision support tool called PRISM (Predictive Risk Intelligence SysteM). PRISM also allows the user to view integrated information from primary, acute, social services, behavioral health, and LTSS payment and assessment data systems. The state added Medicare data to its data warehouse and uses linked Medicare and Medicaid data to identify Medicare-Medicaid beneficiaries with the highest prospective risk scores for enrollment into its health home program.

If an integrated Medicare and Medicaid ACO model serves Medicaid beneficiaries accessing facility- or community-based care, CMS could consider how to support states in assisting nursing facilities, physicians, specialists, and hospitals to transfer time-sensitive Medicaid data that is needed to effectively manage care and support transitions across acute, facility, and community-based settings. Outside of limited care transitions programs operating in states today, hospitals, nursing facilities, and community agencies serving Medicaid LTSS users do not often have capabilities necessary to integrate data across inpatient, post-acute, and LTSS settings. Without extension of Office of the National Coordinator for Health Information Technology (ONC) Meaningful Use program to Medicaid LTSS providers or development of new EHR infrastructure funding, both states and providers will be hard pressed to secure the resources needed to create the data exchange platforms that are necessary to support effective care transitions for Medicaid LTSS.

Another issue for CMS consideration is that some Medicaid MCOs have experience and achieved success in using integrated data for program management and oversight, care coordination, risk stratification, budgeting. As the Financial Alignment Initiatives move toward implementation, more plans serving as Medicare-Medicaid Plans (MMPs) will strengthen this capacity. If CMS includes Medicaid MCOs in ACO models for Medicare-Medicaid beneficiaries, it could require that participating MCOs help providers understand and use patient data.

Question 5

What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

A unified payment model would establish a methodology for shared accountability for savings and costs at the outset. States and CMS have some experience in working together to develop unified payment approaches for capitated Financial Alignment Initiatives. A few states have finalized their payment methodology and risk sharing structures, but it should be noted that developing these comprehensive and complex methodologies is very challenging. Few existing models offer states and CMS guidance on building a capitated payment or shared savings methodologies that blend Medicare and Medicaid funding streams and that encompass primary, acute, behavioral health, and LTSS. Medicare-Medicaid beneficiaries are a very heterogeneous population with a wide range of health needs; however, only a small number of these beneficiaries are heavy users of services in both programs, underscoring the importance of developing targeted approaches to capture the highest-need, highest-cost subset within a state.

CMS and states developed a coordinated shared savings approach for Washington State's MFFS Financial Alignment Initiative. While a coordinated approach may be administratively easier than combining payment rates for separate services and programs, it could create a large administrative burden on states and ACOs to track and calculate shared savings across each programs. A coordinated shared savings arrangement would also require a clear process to prevent cost-shifting across, a strong foundation for shared accountability, and incentives for providing care that is driven by individuals' preferences as instead of providers.

In addition to examining the benefits and challenges of a unified versus a coordinated payment approach, CMS may want to consider the following questions to guide financial arrangements:

- Does the financial arrangement prevent cost-shifting across systems? For example, do hospitals, nursing facilitates, or community providers have a financial advantage to retain or release individuals from their care?
- Do providers have financial incentives to provide care coordination across the full spectrum of essential services? If different providers are responsible for Medicare- or Medicaid-only services, there may be little incentive to coordinate.
- Does the methodology ensure that providers across different systems and settings receive savings that are proportionate to their investment in care?
- If an ACO is responsible for both Medicare-only and Medicare-Medicaid beneficiaries, how does Medicaid capture appropriate Medicaid savings?
- Are both Medicare and Medicaid rates risk-adjusted? For example, if only Medicare services are risk adjusted by diagnoses, this could lead to a disproportionately small share of savings for Medicaid. This could be most impactful on enrollees who need LTSS that allow them to live at home and in the community.
- Does the financial arrangement promote HCBS instead of institutional based care? CMS may consider how ACO providers can become involved with existing state initiatives such as Money Follows the Person or nursing home diversion programs to obtain additional resources to promote cost-effective care in the community.

Section D - Other Approaches for Increasing Accountability

CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

Question 1

A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns.

Are there models to consider that better integrate community-based services beyond the traditional medical system?

As mentioned above, states are the leading innovators in improving integration of community-based services with the traditional medical system. Examples of current approaches include:

- Financial Alignment Initiative. As of February 2014, most of the Financial Alignment Initiatives approved by CMS are capitated models in which Medicare-Medicaid Plans (MMPs) will coordinate Medicare and Medicaid acute, physical health, behavioral health, pharmacy, and

LTSS. For many Medicare-Medicaid beneficiaries, this will be the first time that LTSS is coordinated with other health care services. Programs have stringent requirements—developed primarily by states—to put a care team in place that includes the beneficiary, providers, and other people selected by the beneficiary to develop a service plan to meet the beneficiary's needs as identified in comprehensive clinical and functional assessment. Many states have chosen to enhance and refine current care coordination functions they already have in place for Medicaid beneficiaries. Some states require plans to contract with community supports. For example, Ohio will require MMPs to contract with Area Agencies on Aging to coordinate HCBS waiver services for beneficiaries over age 60. California will require MMPs to contract with county-based specialty mental health plans and substance use disorder agencies, as well as county social services agencies to coordinate in-home supportive services.

- Rebalancing strategies. The ACA provided states with new opportunities (e.g., the Balancing Incentive Program, Community First Choice, etc.) to move individuals to or support them in the community, advancing states' already robust rebalancing efforts.

- MLTSS. As described above, MLTSS provides states an opportunity to use health plan contracts to better coordinate and promote use of HCBS. States can use MLTSS contracts to advance policies to better coordinate medical, behavioral health and LTSS care including: transition policies; network adequacy; care/service coordination; member education; member complaint resolution; reporting; and performance measurement and quality improvement.

- Program of All-Inclusive Care for the Elderly (PACE). PACE is a managed, provider-based program in 29 states that serves more than 20,000 frail, elderly Medicare and Medicaid beneficiaries. Often considered the first truly integrated program for Medicare-Medicaid beneficiaries, the PACE care team is interdisciplinary and manages physical health, behavioral health, pharmacy and LTSS. PACE blends separate capitation payments from and provides full benefits for Medicare and Medicaid. PACE programs receive fixed monthly payments from Medicare and Medicaid for individuals enrolled in the program. These payments are pooled at the program level, have strong incentives to proactively address each individual's specific needs to improve health and reduce the need for acute care and long-term institutionalization. PACE organizations are fully accountable for the quality and cost of all care provided both directly and through contracted providers, as well as the consequences of not providing needed services or providing community-based as appropriate.

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RE: Request for Information: Evolution of ACO Initiatives at CMS

Dear Jonathan and Patrick:

Thank you for issuing the Request for Information seeking input with regard to both a second round of applications for the current Pioneer ACO Model and new ACO models that encourage greater care integration and financial accountability. These programs have the potential to play a crucial role in transforming the future of healthcare delivery across the country, and your willingness to seek input on the programs and to provide adequate time for that input is most appreciated.

The following contains detailed responses to each of the topics on which the RFI solicited input. I would be happy to answer any questions you may have about these recommendations or to provide any additional information you or your staff may have about them.

I. Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. Second Request for Applications for the Pioneer ACO Model

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

It is likely that many health care organizations would be interested in applying if the details of the program were changed in ways that would support significant redesign of care delivery and more predictable payment. Key changes that would encourage participation include:

- Asking beneficiaries to designate their preferred primary care practice, and basing the Pioneer ACO's accountability on the beneficiaries who designated a PCP who is part

of the ACO. CMS allows new Medicare enrollees to designate the ACO as their primary care provider, but does not allow other beneficiaries to do so. Beneficiaries could still be allowed to change primary care practices at any time, so this requirement would not restrict their choice. Beneficiaries who do not designate a PCP in the ACO, or who indicate they do not want their care to be coordinated by the ACO would not be included in the ACO's accountability; this would avoid forcing beneficiaries to switch PCPs simply to avoid being part of the ACO.

- Defining a population-based payment/budget amount for the ACO in advance, with adjustments made based solely on (1) changes in the health status of the participating beneficiaries and (2) changes in Medicare fee schedule amounts that increase or decrease spending independently of actions taken by the providers in the ACO.
- Increasing risk-adjusted population-based payment levels in future years based on the MEI, rather than resetting the baseline after three years as is done today, since the current approach essentially wipes out any benefit to the ACO of the savings it achieved during the previous years.
- Defining quality measures and target levels for the ACO in advance, avoiding changes to the quality measures or targets mid-stream, and using the measures to protect against declines in quality rather than expecting the ACO to make significant improvements in quality at the same time as work is being done to reduce costs.

Details on how to operationalize these changes can be found in *Using Partial Capitation as an Alternative to Shared Savings to Support Accountable Care Organizations in Medicare*, which is available on the Center for Healthcare Quality and Payment Reform website at http://www.chqpr.org/downloads/PartialCapitationPaymentforACO.pdf.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

CMS should not impose any restrictions on the number or locations of applicant organizations; CMS should accept any organization that wishes to participate in its payment models and that meets the conditions of participation, It is inappropriate to give one provider in a community access to a different payment approach and prohibit others in the community from also participating if they wish to do so, and it is inappropriate to allow beneficiaries in some communities to benefit from improved care delivery, while prohibiting others from gaining those same benefits.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

As noted above, key changes that would encourage participation include:

- Asking beneficiaries to designate their preferred primary care practice, and basing the Pioneer ACO's accountability on the beneficiaries who designated a PCP who is part of the ACO. CMS allows new Medicare enrollees to designate the ACO as their

primary care provider, but does not allow other beneficiaries to do so. Beneficiaries could still be allowed to change primary care practices at any time, so this requirement would not restrict their choice. Beneficiaries who do not designate a PCP in the ACO, or who indicate they do not want their care to be coordinated by the ACO would not be included in the ACO's accountability; this would avoid forcing beneficiaries to switch PCPs simply to avoid being part of the ACO.

- Defining quality measures and target levels for the ACO in advance, avoiding changes to the quality measures or targets mid-stream, and using the measures to protect against declines in quality rather than expecting the ACO to make significant improvements in quality at the same time as work is being done to reduce costs.

B. Population-Based Payments:

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

A standard element of most commercial global payment arrangements is a Division of Financial Responsibility (DOFR), through which the provider and payer agree on those specific services for which the provider will be accountable and those for which the payer will retain accountability. CMS should provide this same flexibility for ACOs.

ACOs should also be able to select different FFS reduction amounts for different types of providers as well as for Part A vs. Part B services. For example, in cases where a provider's services are going to be completely redesigned, a 100% population-based payment might be preferable to a mix of FFS and population-based payments, whereas in other cases, 100% FFS payments may be the most appropriate.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

ACOs should have the flexibility to receive population-based payments for any provider that is delivering services to the ACO's patients.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

Yes, CMS should reconsider this requirement. A Pioneer ACO will have great difficulty redesigning the way care is delivered in order to generate significant savings if the underlying payment system is still based on fee for service as it is under a pure shared savings model. In contrast, the ACO would have much greater ability to redesign care and achieve savings with true population-based payment. Consequently, the fact that a Pioneer ACO has been unable to generate savings under a shared savings arrangement does not mean it will be unable to succeed under a population-based payment.

Financial reserve requirements should be limited to the minimum amounts necessary to ensure that the ACO can cover normal variation in the cost of services delivered by participating providers in between disbursements of the population-based payments. Setting high requirements for financial reserves will make it more difficult for small provider organizations to participate than for larger organizations.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

CMS has designed its current approach to population-based payments in a way that is severely biased against physician-led ACOs. Because the payments only replace the payments made to the providers who are part of the ACO, a Pioneer ACO led by a large health system could receive a large population-based payment in place of both inpatient payments and professional fees, but a Pioneer ACO led by a physician group or IPA could only receive a small payment based on professional fees, while the hospitals continue to be paid as they always have.

A growing number of physician groups and IPAs have the capability to accept a global payment and pay claims to hospitals and other providers, and they should have the ability as a Pioneer ACO to obtain a population based payment in place of all fee for service payments to all providers serving their patients if they wish to do so.

Details on how to implement this are described in *Using Partial Capitation as an Alternative to Shared Savings to Support Accountable Care Organizations in Medicare*, which is available at http://www.chqpr.org/downloads/PartialCapitationPaymentforACO.pdf.

II. Evolution of the ACO Model

A. Transition to Greater Insurance Risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

The goal of the ACO program should be to enable healthcare providers to accept as much *performance* risk as possible, without being forced to take on *insurance* risk. "Insurance risk" is the variation in costs due to the number and types of health problems in a patient population; "performance risk" is the variation in costs due to the way those health problems are treated.

Interpreted literally, the term "capitation with insurance risk" means paying a provider organization a fixed amount per patient without regard to the patients' health status. Medicare does not even do this with Medicare Advantage plans (a Medicare Advantage plan receives a risk-adjusted payment from CMS based on the health characteristics of its members), so using capitation (or any other non-risk adjusted payment approach) would be an inappropriate way to pay providers and would create yet another bias in favor of larger and hospital-led provider organizations.

Instead, CMS should offer ACOs the ability to be paid through a risk-adjusted global payment for all of the providers in the ACO instead of individual fee for service payments from

Medicare. The providers would not be taking on *insurance* risk, because the payments would be risk adjusted. However, the providers would be taking on full performance risk, since all of the services provided to the patients would need to be paid from the pre-defined global payment.

Details on how to implement this are described in *Using Partial Capitation as an Alternative to Shared Savings to Support Accountable Care Organizations in Medicare*, which is available at http://www.chqpr.org/downloads/PartialCapitationPaymentforACO.pdf.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

No ACO should be expected to take on full insurance risk. However, ACOs that are willing to accept performance risk need the ability to redesign *all* aspects of patients' care, including professional services, inpatient services, and medications. Consequently, all or part of the types of services covered by Medicare Parts A, B, and D should be included in the ACO's payment.

3. Are there services that should be carved out of ACO capitation? Why?

As in the Division of Financial Responsibility in commercial global payment contracts, each ACO should have the ability to define specific services that it wants to have included and excluded from a global payment. Because of the dramatically different structures of healthcare markets in different communities, providers in some communities will be able to accept accountability for a smaller range of services than will providers in other communities. If a provider is willing and able to help CMS control a *portion* of Medicare costs, but it cannot take responsibility for *all* Medicare spending, CMS should support that, rather than CMS taking an "all or nothing" approach to ACO contracting.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

In order to truly take accountability for costs, most ACOs will need and want to have the ability to pay non-ACO providers directly, rather than having those providers paid directly by Medicare. The ACO should be permitted to work out the details of agreements with these providers, since the ACO will be accountable for both the quality and cost of the services the beneficiaries receive.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk?

ACOs should not be expected to take on full insurance risk. As in the Medicare Advantage program, ACOs should be allowed to modify cost-sharing requirements for patients to enable more effective coordination of care and encourage use of high-value services.

Details on how to implement appropriate incentives for beneficiaries are described in *Using Partial Capitation as an Alternative to Shared Savings to Support Accountable Care*

Organizations in Medicare, which is available at http://www.chqpr.org/downloads/PartialCapitationPaymentforACO.pdf.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

Since ACOs should not be expected to take on full insurance risk, CMS should work with the National Association of Insurance Commissioners to develop a common set of regulations governing ACOs that do not force them to meet the same standards as insurance companies.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

Since ACOs should not be expected to take on full insurance risk, Medicare should retain responsibility for enrolling Medicare beneficiaries in the Medicare program and dealing with issues related to insurance coverage, and the ACO should focus on connecting beneficiaries with appropriate providers and services. ACOs will need to develop appropriate capabilities for care management, patient education, shared decision-making, etc. in order to be successful, but CMS should not attempt to prescribe how these capabilities should be implemented.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

ACOs should not be paid using traditional capitation. ACOs should be paid using a risk-adjusted global payment with appropriate risk corridors, risk exclusions, and risk limits.

The method being used by the Pioneer ACO program to set expenditure benchmarks is highly problematic because CMS uses a benchmark based on an arbitrary combination of national and regional spending trends. Under this methodology, ACOs in high-spending regions could slow Medicare spending growth significantly but still not be credited with "savings," while ACOs in low-spending regions can potentially be credited with savings even if they have above-average rates of spending growth. Moreover, the benchmark methodology does not adjust for higher-than-average updates in Medicare fees in a region due to geographic adjustment factors or other region-specific policies.

In theory, using a local benchmark would be fairer than a national benchmark, but the only way to estimate what local spending would have been in the absence of the ACO is to compare it to a comparable population in the local market, and if the ACO is large enough, or if there are multiple ACOs in the market, there may be no "comparable" local population. In fact, as more and more providers participate in accountable care arrangements, it will become increasingly difficult for CMS to determine what spending would have been in the absence of those arrangements.

The other major Medicare payment programs do not use this "savings" or "benchmark" approach to setting payment levels. Payment levels in the Physician Fee Schedule (RBRVS), the Inpatient Prospective Payment System (DRGs), the Outpatient Prospective Payment System (OPPS), etc. are all set prospectively and updated each year to account for inflation, changes in technology, etc. CMS needs to define a similar methodology for ACOs. For example, ACOs could receive a population-based payment that is based on its expenditures during the prior year, updated by an inflation factor such as the MEI, and adjusted based on changes in the risk profile of the beneficiaries, changes in Medicare fee schedules, introduction of new technologies, new evidence about appropriate care, etc. This would give CMS a predictable amount of spending with affordable increases from year to year, and it would also give the ACO a predictable budget to work with.

Details on how to implement this kind of prospective payment system for ACOs are described in *Using Partial Capitation as an Alternative to Shared Savings to Support Accountable Care Organizations in Medicare*, which is available at http://www.chqpr.org/downloads/PartialCapitationPaymentforACO.pdf.

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

There is no perfect method of risk adjustment. Since many ACOs will likely be participating in performance-based payment contracts with Medicare Advantage plans as well as with CMS, it would make sense for CMS to use a common risk adjustment methodology for both ACOs and Medicare Advantage.

CMS has been experiencing problems with risk adjustment in both Medicare Advantage and ACOs because a patient's risk scores inherently increase once the patient joins one of these programs. Providers in ACOs have both a reason and a mechanism for documenting all of the patient's health issues, rather than merely recording the diagnoses needed to justify the particular services they are billing for at a particular time under the fee for service payment requirements. The solution to this is not to eliminate risk adjustment entirely or to use flawed methods (such as "risk adjusting" based on the prior expenditures on that patient), but rather to modify the risk adjustment methodology to solve the specific problems CMS has been experiencing. Most of the increase in RAF (risk) scores under the HCC methodology likely occurs because patients are being coded for the first time to document conditions that they had long before they entered the ACO or MA program. Rather than allowing these preexisting but newly documented conditions to suggest that a beneficiary's health status has worsened by comparing the updated RAF score to the incomplete RAF score that was computed prior to the beneficiary entering the ACO program, the beneficiary's *baseline* RAF score should *also* be increased using the newly documented but pre-existing conditions. That way, only *new* health problems would actually increase the RAF score and signal the need for a higher payment to the ACO.

10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

ACOs should have the flexibility to adjust cost-sharing for patients based on the specific types of care changes the ACO is trying to implement. For example, if an ACO is focusing on an initiative to help patients with COPD avoid exacerbations, it would likely want to reduce cost-sharing on long-acting bronchodilators and nebulizers, whereas if the ACO is focusing on ways to use more cost-effective testing for ischemic heart disease, it might want to reduce beneficiary cost-sharing for tests ordered by physicians who use decision supports and shared decision-making tools based on appropriate use criteria. No single change in benefits will be appropriate, because the needs of Medicare beneficiaries differ from region to region and the opportunities for savings that ACOs will pursue will also differ.

ACOs should also be permitted to offer rewards to beneficiaries who adhere to care plans or achieve health improvement goals, either in the form of cash, reduced cost-sharing, or access to additional services.

Details on how to implement appropriate incentives for beneficiaries are described in *Using Partial Capitation as an Alternative to Shared Savings to Support Accountable Care Organizations in Medicare*, which is available at http://www.chqpr.org/downloads/PartialCapitationPaymentforACO.pdf.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

ACOs should not be expected to take on full insurance risk. Giving an ACO full insurance risk creates an incentive for the ACO to avoid patients with multiple or expensive health conditions. Conversely, paying the ACO on a risk-adjusted basis encourages the ACO to treat sick patients and to find higher-quality, lower-cost approaches to treatment.

Many of the current fraud and abuse rules can and should be relaxed or waived entirely for ACOs receiving risk-adjusted population-based payments. For example, since population-based payment will not vary based on how many services are delivered or how many procedures are performed, there would no longer be any need to ban self-referrals to physician-owned facilities; in fact, physician-owned facilities could enable more efficient, higher-quality delivery of care by giving the physician direct control over all aspects of the delivery of care.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

ACOs should not be expected to take on full insurance risk. Risk adjusted payments protect the ACO against adverse selection and protect beneficiaries against being excluded from care because of pre-existing conditions.

If ACOs are going to be successful, CMS needs to support them by educating beneficiaries about the value of using a coordinated group of providers. While beneficiaries should have the freedom to change providers when they believe they are receiving poor care, they should be encouraged to select primary care providers, specialists, and hospitals who work together in a patient-centered, coordinated way.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

ACOs should not be expected to take on full insurance risk. Under any method of paying ACOs, the primary method of aligning beneficiaries to ACOs should be the beneficiary's voluntary designation of that ACO to provide the beneficiary's care (or designation of one of the ACO's primary care providers as the beneficiary's medical home). Claims-based attribution, which is already seriously flawed as an approach, will become increasingly problematic as more providers use flexible payments to deliver care in non-traditional ways. If a patient is getting good care without having to make billable office visits to a physician in an ACO, the ACO should be able to get "credit" for such a patient even if there are no billable visit claims to trigger a claims-based attribution methodology.

Details on how to structure a system whereby beneficiaries elect to participate in an ACO are described in *Using Partial Capitation as an Alternative to Shared Savings to Support Accountable Care Organizations in Medicare*, which is available at http://www.chqpr.org/downloads/PartialCapitationPaymentforACO.pdf.

B. Integrating Accountability for Medicare Part D Expenditures

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

In many cases, if a beneficiary uses an appropriate medication that is paid for under Part D, it can enable the beneficiary to avoid much more expensive services under Part A or Part B. In other cases, an appropriate set of Part B services can enable a beneficiary to avoid the need for expensive medications under Part D. In other words, an expense under Part D can generate savings in Part A or B, and an expense under Part B can generated savings under Part D. However, if the revenues and costs for Parts A, B, and D are kept segregated, there is no way to achieve these net savings.

Consequently, CMS needs to create a mechanism whereby ACOs can make cost sharing and coverage decisions for pharmaceutical benefits with recognition for the impacts of those decisions on *total* Medicare spending, not just Part D.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

ACOs should not be expected to become pharmaceutical insurance companies merely to enable integration of pharmaceuticals into overall efforts to redesign care.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

ACOs should not be expected to accept full risk for pharmaceutical costs or full risk for any type of cost. If an ACO has created capabilities such that it is willing and able to take on insurance risk, CMS could consider contracting with the ACO based on that higher level of risk, but ACOs that cannot do so should not be precluded from taking on performance risk and helping reduce Medicare spending. Both the price of pharmaceuticals and the health conditions of beneficiaries are outside the control of an ACO, and they should be treated as insurance risk. Conversely, the types of drugs prescribed to treat a patient's conditions is an appropriate part of the performance risk that ACOs should be expected to manage.

C. Integrating Accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

Depending on the community, the providers who care for the majority of Medicaid recipients may be very different from those who care for the majority of Medicare beneficiaries, so it would not be possible to simply assume that a Medicare ACO would have the same ability to manage care for Medicaid recipients as for Medicare beneficiaries. In particular, maternity care is one of the largest components of healthcare spending in Medicaid, but an almost non-existent component of the Medicare program. A Medicare ACO is most likely to be able to take accountability for Medicaid outcomes for dual-eligible individuals.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare- Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

It would be extremely difficult, if not impossible, for an ACO to accept accountability for Medicaid-only beneficiaries if they are "attributed" to the ACO using the same types of rules that CMS is using for Medicare. The fact that so many Medicaid recipients only receive benefits for a limited period of time means that an individual may no longer be on Medicaid by the time they are attributed to a provider. Most Medicaid managed care plans require Medicaid recipients to choose a primary care provider (or assign them to a provider if one is not chosen), and CMS would need to allow Medicaid ACOs to use a similar requirement in order for them to be successful. For young women on Medicaid, their primary source of care may come from a maternity care provider, and so visits to a maternity care provider should be an option for the attribution or assignment of patients to the ACO as well as visits to a primary care provider.

Similarly, the Medicaid outcomes for which an ACO can reasonably accept accountability are those that are directly related to services that the ACO can provide during the time that the Medicaid beneficiary is (a) eligible for Medicaid and (b) receiving care from the ACO's providers.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

States can play several key roles in fostering coordination of care:

- States can use accountable payment models to pay ACOs, not only through the Medicaid program, but also for state employees.
- States can facilitate discussions among providers and payers to agree on common approaches to payment (but not payment amounts) under the state action exemption for antitrust.
- States can ensure that large provider organizations do not refuse to contract for services with smaller ACOs that cannot provide a full range of services themselves.
- States can require that health plans release claims data to an all-payer claims database so that providers can develop plans for multi-payer payment and delivery reforms.
- States can ensure that providers forming ACOs are not subject to unnecessary or burdensome insurance regulations.
- States can control unreasonable pricing or payment arrangements or anti-competitive behavior by health plans or hospitals.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

It is inefficient to expect every ACO to independently develop the capability to merge and analyze multiple sources of claims data. Moreover, requiring this capability will make it more difficult for smaller, physician-led ACOs to participate. CMS should proactively support the efforts of multi-stakeholder Regional Health Improvement Collaboratives to become Qualified Entities, to merge Medicare, commercial, and Medicaid claims and combine them with clinical registry data, and to provide analyses to providers interested in forming ACOs as well as to existing ACOs to help them succeed. In addition to providing timely, affordable access to data, CMS needs to provide funding to support both the analytic work and technical assistance to physicians and hospitals in using the analysis to improve care and succeed under new payment models.

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

For dual eligible individuals, it is inappropriate for the state and CMS to try and calculate and pay "shared savings" separately, since some Medicare expenditures can help avoid a Medicaid expenditure, and vice versa. The only way to create a truly *patient-centered* payment approach to support these individuals is for CMS and states to acknowledge that they are each "partial payers" for the patients, and to combine their separate payments into a single, risk-adjusted global payment to the ACO. CMS and the states can then decide how to divide any savings between them, rather than forcing the ACO to do so.

For individuals who are on Medicaid or Medicare but not both, states and CMS can pay the ACO separately for their respective beneficiaries, but they should do so using payment methodologies that are as similar as possible, so the ACO can make changes in care based on the patients' needs, not based on the source of their payment.

D. Other Approaches for Increasing Accountability

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

If all of the providers in a community voluntarily come together to manage overall outcomes for the residents of a community, CMS could support that through the same mechanisms it uses to support any other ACO. However, a "community ACO" should only be a *voluntary* effort by the community, it should not be imposed on the providers in a community either directly or indirectly by CMS, e.g., by setting minimum thresholds for the number of beneficiaries in an ACO that make it impossible for multiple ACOs to form in a community. In most cases, it will be preferable for beneficiaries to have a choice of ACOs, and CMS should not preclude or discourage that.

Community-based services can be part of what any ACO offers or supports if CMS provides the ACO with a sufficiently large and flexible population-based payment; it is not necessary to have a community-wide ACO for that to be possible.

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

One of the biggest weaknesses of the current shared savings payment system used by CMS to support ACOs is that it does not actually change the underlying fee for service payment system. This makes it extremely difficult for providers to significantly redesign the way they deliver care. Conversely, other CMS initiatives, such as the Comprehensive Primary Care Initiative, attempt to hold individual providers accountable for the total costs of care for beneficiaries, even though those providers cannot control or even influence all aspects of Medicare spending. Consequently, both the ACO program and other CMS payment initiatives would benefit by not only allowing, but encouraging the use of payment reforms for primary care practices, specialists, hospitals, post-acute care providers, etc. inside of ACO payment structures.

For example, CMS could make medical home payments to primary care practices, condition-based payments to specialists, and episode payments to hospitals that are part of an ACO. The overall ACO accountability for total cost would help ensure, for example, that episode payments did not cause more episodes to be delivered, while the shared savings

calculation to the ACO would be adjusted to account for any extra payments made to providers in the ACO under the individual payment models (e.g., the non-visit based payments used in the Comprehensive Primary Care Initiative) and/or any discounts provided to CMS through the individual payment models (e.g., those included in the Bundled Payments for Care Improvement Initiative). This "layering" of payments to an ACO would be analogous to the way many physician groups, physician IPAs, physician-hospital organizations, and health systems "sub-capitate" portions of an overall global payment to subgroups of providers.

CMS should also make other payment models available to ACOs besides the current shared savings model. Although Section 1899 of the Social Security Act is entitled "Shared Savings Program," Section 1899(i) explicitly gives CMS the authority to "use other payment models," including a partial capitation model. These other payment models would likely be more attractive to many physician groups than the pure shared savings model that CMS is currently using. Details on how to implement a partial capitation payment program are described in *Using Partial Capitation as an Alternative to Shared Savings to Support Accountable Care Organizations in Medicare*, which is available at http://www.chqpr.org/downloads/PartialCapitationPaymentforACO.pdf.

E. Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

One of the biggest barriers that payers face in arranging "ACO" contracts with providers is that comparable ACO payment structures are not available from CMS. CMS may feel it is improving on commercial ACO contracts when it defines the way that Medicare will contract with ACOs, but using a different payment structure or different administrative requirements than other payers or using a payment structure that is not acceptable in the commercial marketplace means that CMS is creating extra costs and complexity for the ACO and its providers that will reduce their ability to focus on the primary goals of care improvement and cost reduction.

In order to encourage participation by payers that are not currently supporting ACOs, CMS could offer more favorable Medicare requirements or payment terms to ACOs that have multiple payers participating.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

CMS could encourage alignment of quality measurement among payers in several ways.

First, CMS should align its own quality measurement programs. In both its ACO and CPCI programs, CMS has chosen different quality measures than it uses in its Medicare Advantage 5 Star Quality Rating program; this means that Medicare Advantage plans that want to support an ACO or CPCI physician practice typically want to use 5 Star measures instead of or in addition to the CMS measures.

Second, CMS should allow case-by-case changes in the quality measures it requires of individual ACOs in order to align with the measures that commercial and Medicaid payers want

to use for those ACOs. It is unreasonable for CMS to expect other payers to adjust their quality measures if CMS is not willing to do so itself.

Finally, CMS should give ACOs the flexibility to propose quality measures that are directly related to the aspects of care delivery where the ACO will be focusing its cost containment efforts. Requiring the ACO to focus on quality improvement for patient conditions or services different from where the ACO is attempting to reduce costs not only forces the ACO to spread its care transformation resources more thinly than would be desirable, it also means that CMS is not measuring quality in the areas where beneficiaries have the most potential to be harmed by cost reduction efforts.

Details on how to use quality measures to adjust ACO payments are described in *Using Partial Capitation as an Alternative to Shared Savings to Support Accountable Care Organizations in Medicare*, which is available at http://www.chqpr.org/downloads/PartialCapitationPaymentforACO.pdf.

I hope the above input is helpful. As I indicated at the beginning of this letter, I would be happy to answer any questions you may have about these recommendations or to provide any additional information you or your staff may have about them. I would also be more than willing to provide any assistance to you in incorporating these recommendations into your regulations and program guidelines.

Sincerely,

Harold D. Miller
President and CEO

BACKGROUND

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Please select the option that best describes you.

- Part of both a Medicare ACO and a Commercial ACO

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

Part A: Interest in Additional Pioneer ACOs

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model?

No

A. Why or why not?

About CHE Trinity Health
CHE Trinity Health appreciates the opportunity to submit feedback to the Center for Medicare & Medicaid Innovation (CMMI) and the Centers for Medicare & Medicaid Services (CMS) on the evolution of Accountable Care Organization (ACO) Initiatives. CHE Trinity Health is the second-largest Catholic healthcare delivery system in the nation, serving people and communities in 20 states from coast to coast with 82 hospitals, 88 continuing care facilities, and home health and hospice programs that have more than 2.3 million visits annually. It was formed in May 2013, when Trinity Health and Catholic Health East completed their consolidation to strengthen their shared mission, increase excellence in care, and advance transformative efforts with their unified voice. With annual operating revenues of about $13.3 billion and assets of over $19 billion, the new organization returns more than $800 million to its communities annually in the form of charity care and other community benefit programs. CHE Trinity Health employs nearly 86,000 people, including nearly 4,000 physicians. CHE Trinity Health is currently participating in 5 Shared Savings Plan (SSP) ACOs and was part of one Pioneer ACO that withdrew from the Program. We are committed to developing more ACOs over this year, but have significant concerns as described in these comments.

Specific response to Part A
Organizations are not gravitating toward the Pioneer ACO model because the downside risk is not outweighed by the opportunity for economic gain – the business case is not compelling. Contributing factors to this include patient turnover, floating benchmarks, and inconsistency in data timing, and accuracy. In particular, concerns about decedent adjustment methodology have made this model highly unpredictable, thus resulting in inappropriate risk.

If CMS developed a different methodology, there may be interest from other organizations in participating in the Pioneer model. An example of an alternative methodology would be as follows:

Option A: A model that offers a larger share of savings in the first three periods in exchange for a predetermined trend rate that is lower than historical trend. For example, 80% of savings from historical average in exchange for a guaranteed trend rate of -1% for three years. Alternatively, the model could include downside risk but with a cap of 1% or something similarly low.

2. **If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?**

   Accept all organizations that meet the qualifying criteria

   A. **What are the advantages and/or disadvantages of either approach?**

      CMS should accept all qualified applicants. Seeking as many participants as possible will increase experience, improve analytic results, encourage more transformation, and create more savings for CMS. Also, testing these models with as many organizations as are willing and able will ensure the results are as broadly generalizable as possible.

3. **Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?**

   Yes

   As the Pioneer benchmark and target methodologies evolve, there is great uncertainty about the model. There is extreme volatility in the calculations driven by changes in mortality rates. Even a small number of differences in deaths in the population from year to year triggers results that call into question the very validity of the benchmark and target methodologies.

   We believe that it is necessary to find a simpler methodology for establishing benchmarks for both programs. **In particular, participating Pioneer ACOs should have a defined benchmark and target at the beginning of the year that is fixed**. This will afford the ACO the opportunity to track its performance and project ultimate success with accuracy.

Part B: Population-Based Payments for Pioneer ACOs

1. **Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP?**

   Yes

   A. **Why or why not?**

      CHE Trinity Health believes that organizations will need to *gradually* transition from FFS payments to PBP. Such a transition process is essential. Many organizations will test their financial risk management capabilities and a large initial reduction could discourage many of these organizations from participating. Already, providers are dividing into two camps—those still reliant on FFS and those testing out alternative payment models, and as such, it is vital that CMMI continue to support and engage with those in the first camp to

prove the success of these new payment and delivery models. The success (or failure) of already high-performing organizations does not prove the effectiveness of any one model. Rather, CMMI should work to ensure that a support structure and gradual phase-in process exists for all organizations as they become accountable for the care and cost of their patient population.

2. **Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?**

   Yes

   A. Why or why not?

   For delivery reform to be impactful, all facets of the healthcare system should be part of value-based payment. In addition, DME is a significant expenditure and is often a target of fraudulent activity, a potential for huge savings exists in this area. ACOs are already responsible for the Part B spending of their aligned population, and allowing for a DME supplier to become a partner that works hand-in-hand with the ACO will further encourage value-based relationships and a shift the mindset of suppliers towards an accountable model.

3. **Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves?**

   Yes

   A. Why or why not?

   CHE Trinity recommends that CMS and CMMI reconsider the requirement that Pioneer ACOs meet a specific threshold of savings to be eligible for PBPs. We recommend that, instead, CMS and CMMI establish clear requirements for financial reserves or a robust reinsurance policy or develop alternative approaches that recognize the capital reserves already present in some health care providers balance sheets.

4. **Should any additional refinements be made to the current Pioneer ACO PBP policy?**

   Yes

   A. Why or why not?

   The policy would be improved if CMS established an alternative reconciliation methodology that converts the current PBP approach – which is really a cash flow mechanism – to a true capitation approach.

SECTION II: Evolution of the ACO Model

Part A: Transition to Greater Insurance Risk

1. **Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations?**

   Yes

   A. What are the potential benefits and risks to the Medicare program and beneficiaries?

   General Recommendations

   The SSP Program and the Pioneer Model have attracted almost 400 participants who are committed to producing better health, better care and reduced costs for Medicare beneficiaries. Experience to date has demonstrated that ACOs can improve quality and decrease costs, even in one-sided risk models. CHE Trinity Health is currently participating in 5 SSP ACOs and was part of one Pioneer ACO that withdrew from the Program. We are committed to developing more ACOs over this year. However, we also believe that there are significant current and potential problems that need to be addressed to ensure ongoing viability of ACOs.

   It is critical that CMS/CMMI continue to evolve the ACO model to ensure existing participants stay involved and to entice new participants to join. It was to be expected that the first two years of operation of both ACO initiatives would reveal many uncertainties, surprises and need for significant adjustments. **The most significant immediate adjustment we believe is to recognize that the original expectation that all ACOs move to two-sided risk after three years is not a viable policy.** We believe that given the many current issues with the program, insisting on movement to two-sided risk is premature and will result in the exit of most ACOs from the programs.

   Similarly, lack of clarity from CMS about whether movement to downside risk will be required, or requiring it after two years will limit participation in the next three year period. **Therefore we recommend that CMS eliminate the requirement to move to downside risk following three years of no risk.** At the same time we believe that CMS must address the following critical current concerns to ensure ongoing robust participation in the program: .

   1. Year to year instability of the aligned population;

   2. Uncertainty about a clear payback model and the impact on the investment in care coordination;

   3. Trend calculations using national trend numbers;

   4. Lack of understanding of benchmark and target methodologies;

   5. Uncertainty about whether CMS will continually decrease targets based on achieved savings through rebasing;

   6. Changing quality metric specifications and benchmark methodologies; and

7. Uncertainty about which interventions are effective.

In short, the program from both CMS and ACO's perspectives is too immature at this time to expect providers to accept significant risk. **However, it is in everyone's interest to allow the program to continue to evolve and grow**. We believe these issues must be addressed to achieve that end, and offer respective approaches for each area of concern below. Some of these issues could be addressed through revised regulations. We also understand that the statutory language of Section 3022 (ACO section) may limit CMS' ability to adjust significant parameters through regulations. However, CMS has demonstrated appropriate use of Section 3021 authority to test alternative approaches within the SSP program in the Advance Payment ACO Model Test. **We believe that many of the alternative approaches described below could be similarly tested using the 3021 authority, thus bringing significant flexibility to the SSP**. We also believe that the very nature of the SSP program as an entirely new approach to financing and delivering care makes it a most appropriate place to use 3021 authority to rapidly test models. These successful models could then be scaled nationally as part of a refined SSP program.

1. <u>Year-to-year instability of the aligned population</u>

A stable population is essential to the actuarial risk management that CMS expects ACOs to demonstrate. We recommend ACO models be adjusted such that Medicare beneficiaries be permitted to "opt in" to an ACO. This could be done by creating a simple mechanism to allow patients to attest to their interest in being eligible for advanced care management services within the ACO.

CHE Trinity Health recommends that future ACO models use a corridor approach to the plurality algorithm used to assign beneficiaries to an ACO. Currently, attribution is determined by the preponderance of Medicare claims with a given ACO provider using a bright line test. Minor changes in the distribution of services from year to year result in patients being aligned or dis-aligned from an ACO. We suggest that a 10% corridor be established so that if a patient's claims are within 10% of the plurality of claims then the patient would continue to be aligned with the prior ACO. Allowing patients to opt into another ACO could ensure that patients ultimately control where they have their care coordinated.

2. <u>Uncertainty that there is a clear payback model:</u>

ACOs are uncertain about the magnitude of the payback opportunity for many reasons including the seemingly black box benchmark and target setting methodology, frequent changes in the financial targets and ongoing changes in the definition of quality benchmarks. One solution would be to establish a definitive target for the ACO using a fixed trend number, not necessarily related to the actual Medicare trend. (This might require a test using 3021 authority) Another improvement that we recommend is to reduce the Minimum Savings Rate (MSR). We recognize the need to use the MSR symmetrically to keep the ACO programs budget neutral. However, we think that CMMI Section 3021 authority could be utilized to establish a "reinsurance mechanism" to make up for potential shortfalls for CMS that could occur as a result of the asymmetry in financial results that might follow decreasing the sharing threshold to 1%. As an example, if the MSR could be reduced to 1% maximum the CMMI reinsurance model would reimburse the trust fund for any payments that are made to ACOs between the 1% and calculated MSR or a 2% standard MSR.

Because of this uncertainty about earning savings, many ACOs are not investing sufficiently in care coordination to drive significant savings. We encourage CMS to build upon the success it has already achieved in the Advance Payment ACO model where you used the CMMI Section 3021 authority" to test prepayment of savings to ACOs in the MSSP ACO models. CMS could extend this approach to prepay all ACOs care management fees of $10 PMPM. This approach would also be consistent with and a test of the approach of CMS to move toward care management fees for high risk enrollees in 2015.

3. Trend calculations using national trend numbers:

Using national trend numbers without regard to regional variation could be producing results that lead to unrealistic targets in many regions. An example of such influencing factors could be the impact of localized DME bidding, or re-pricing of home care services that have much greater impact in high utilization areas. **CMS should move to regional trends in setting the benchmark. They should also reconsider the use of a fixed dollar amount trend factor as we enter an era of potential negative trends.** Negative trends could result in perverse lower % trend factors in low cost areas – thereby missing the original intent of Congress to give low cost areas higher annual increases.

4. Lack of understanding of benchmark and target methodologies:

On top of all the other uncertainty regarding payment in the program there is great uncertainty about the benchmark and target setting process for both programs. This has been most evident in the Pioneer model where the impact of the decedent factor on benchmark volatility has only gradually been understood by all parties. The reality is that this same volatility underlies the benchmark and target relationships in the SSP program. **CMS should explore the possibility of an alternative approach to establishing benchmarks and targets that is simpler and provides fixed, not fluctuating targets, for ACOs in both programs.**

5. Uncertainty about decreased targets through rebasing:

Many critics of the shared savings approach have noted that it is not a stable approach because shared savings may be entirely recouped through re basing at the end of a defined period. CMS should explicitly recognize that their intent is to not recoup shared savings but rather to be comfortable with gradually decreasing the trend in medical expenses. As an example CMS could establish a policy that leaves 75% of the savings achieved by the ACO in the rebased target. This delivers real savings to CMS but also leaves sufficient opportunity in the target for ACOs to continue reinvesting in care coordination in expectation of achieving a positive financial result.

6. Changing quality metric specifications and benchmark methodologies:

Because of the lack of real experience with quality metrics in the FFS population, the evaluation of quality outcomes for the FFS population is in a very early stage of understanding. Specifications are just now being made available and a fair understanding of the performance expectations for ACOs is just beginning to emerge. Quality performance has a major impact on financial results. There is also widespread regional variation in quality results. **CMS should establish a methodology that allows achievement of success, and payment of earned savings on either an absolute achievement or improvement basis**. Providing many pathways to achieve the quality targets would be consistent with the overall intent of CMS to create a program that involves as many organizations as possible, allows as many to

be successful as possible and encourages ongoing investments by making it easier in early years to earn sufficient funds for reinvestment in care improvement.

7. Uncertainty about what interventions are effective:

While there has been a great deal of investment in new care methodologies, most ACOs are continuing to test new approaches. This is another reason that ACOs will be unwilling to take two-sided risk. CMS could help improve the discovery of new approaches that work and improve cost and quality by rapidly developing and investing more in the ACO Learning System.

2. **What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)**

CHE Trinity Health believes that ACOs at full insurance risk can be responsible for Medicare Parts A, B, and D. It is not logical or appropriate to exclude Part D from a risk arrangement as it fundamentally affects the rest of the care provided and overall outcomes.

We would also like to suggest a model that – while not full capitation – provides many of the benefits of capitation without requiring ACOs to develop the full operational infrastructure of an insurance company or be subject to the extensive regulatory oversight of insurance companies. We call this the "Full Capitation-Equivalent Model."

Full Capitation-Equivalent Track

- An ACO contracts with CMS for the opportunity to collect 95% of the savings compared to a fixed projected claims expense based on the prior three year population experience trended forward using regional trend factors. Targets are set at 98% of the FFS expense providing CMS with some upfront savings. The contract specifies expected quality performance as described previously.
- CMS pays the ACO a monthly payment of $50 PMPM to use to make investments in care coordination and alternative payment arrangements with participating ACO providers.
- CMS pays all claims per usual rates with all participating providers.
- ACO negotiates alternative payment arrangements with ACO providers which may result in increased payments made by the ACO or agreed upon discounts from Medicare FFS rates

- ACO is allowed to collect discounted amount from provider each month – based on claims expense documented in their monthly claims reports and negotiated discounts.
- CMS provides running quarterly reconciliations of ACO performance with payments back to CMS or from CMS to the ACO.
- ACO is required to make CMS whole for the advance payments in any event – this is the limit of their downside exposure.

Advantages – Maintains low cost structure of the ACO, no need to build processing, member service infrastructure and very limited need to hold reserves. The only downside risk to ACO initially would be the need to pay back the advance. It allows ACO to establish the alternative payment agreements with other providers deemed essential to achieve alignment across the network. It eliminates need for both parties to pay claims and the likely complexity associated

with that approach. It provides the full return to ACO of full capitation with positioning them to be regulated as insurers.

We believe that safety-net organizations should receive special consideration for this Alternative model.

Absent an approach like this, the difference between a fully-capitated ACO entity and an MA insurer with regard to reserves, operational capabilities, administrative expenses and regulatory oversight/burden seems minimal. It then becomes just an MA approach where alignment takes the place of enrollment, there is no network limitation and no referrals. While it may be a way to get more FFS beneficiaries the benefit of care coordination it inflicts an unfortunate burden of administrative expenses and complexity for all concerned, including beneficiaries.

3. **Are there services that should be carved out of ACO capitation? Why?**

   NO RESPONSE

4. **What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?**

   NO RESPONSE

5. **What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would NOT be appropriate for ACOs assuming full insurance risk?**

   CHE Trinity agrees that ACOs will need increased flexibility in the regulatory and compliance framework if they assume full insurance risk. We recommend that CMS and CMMI:

   - Utilize a risk adjusting methodology that provides ACOS with a level playing field with MA plans;
   - Evaluate beneficiary access to ACO providers;
   - Eliminate the 3-day stay requirement for skilled nursing facility admission; and
   - Require ACOs to demonstrate financial reserves or a robust ACO reinsurance policy or develop alternative approaches that recognize the capital reserves already present in some health care providers balance sheets.

6. **What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?**

   One major attraction of ACOs that should be preserved is the limited administrative overhead. ACOs are provider-based, closer to their patient and have a long history of actually providing care directly. When considering issues of regulatory oversight or requirements we should be mindful of only adding regulatory burdens, and its resulting administrative expenses, when absolutely necessary.

State licensure for risk bearing entities can be very onerous and costly, and varies dramatically across states. Given that many ACOs operate across state lines, CMS and CMMI should work with states to limit the number of state-specific requirements that ACOs would need to comply with to serve beneficiaries. In addition, we recommend that CMS and CMMI work with states to ease requirements that risk-bearing entities file with the state on an annual basis, given the potential for fluctuation in ACO agreement periods. States that have a less stringent requirement for organized delivery systems should be used as a model.

We believe that all of the waivers that apply to MA plans should apply to a risk-bearing ACO model. There are some key waivers that are not present in the MSSP program that should be added at minimum, a waiver of the skilled nursing facility three day stay requirement, waiver of the home health homebound requirements, an allowance for sharing of internal ACO savings (as opposed to shared savings), in home safety checks prior to procedures, all of the site of service coverage policies that are rooted in the fee-for service system (IRF 60% rule, LTCH 25% rule etc).

7. **Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?**

   See comments above. If ACO's become a second claims payer they will need many of the same additional patient services capabilities.

8. **The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are approaches for setting appropriate capitation rates?**

   CMS should use regional trends in setting the capitation rates. Using national numbers without regard to regional variation could produce results that may not represent real costs in many regions. An example of such influencing factors could be the impact of localized DME bidding, or re-pricing of home care services that have much greater impact in high utilization areas.

   A. What are the advantages and disadvantages of using national expenditure growth trends?

   NO RESPONSE

   B. What about for using a local reference expenditure growth trend instead?

   As noted above we believe this is more appropriate.

9. **What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)**

   CHE Trinity Health believes that risk adjustment should be handled in the same manner for MA and ACOs. Both should have HCC coding increases capped at the underlying rate of change in the FFS population. We believe a chosen methodology should put MA plans and ACOs on a level playing field.

10. **What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes?**

    As it stands the underlying fee-for-service benefit structure applies to ACOs without exception. This precludes ACOs from steering beneficiaries to “in-network” providers, encouraging compliance with physician orders, or selecting lower-cost treatments. To optimize results, ACOs should have the ability to vary copays depending on services and providers is critical to both improving the quality of care and reducing spending. Such flexibility would allow the ACOs to structure the benefits in a way that encourages beneficiaries to seek care that is evidenced-based and at providers of higher value services that will lead to better outcomes. This would generally result in reduced patient responsibility when following ACO referrals etc.

    It would also serve beneficiaries for the ACOs to receive more legal waivers for providing items and services free of charge that might otherwise be considered an inducement. The ACOs need the flexibility to invest in items or services that do not necessarily have current billing codes, but could have a long-term positive impact on the beneficiaries care. PACE is a model for this where, for example, a program can pay to have a wheel chair ramp installed in the person’s home so that they can get out of the house for medical visits, adult day care etc.

    A. **How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?**

       NO RESPONSE

11. **What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?**

    NO RESPONSE

12. **What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?**
    CHE Trinity recommends that ACO marketing material requirements should be "file and use." ACOs whose material is consistently found to be inappropriate or who do not comply should be penalized or removed from the program.

13. **Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology?**

    YES

    A. **What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?**

By allowing beneficiaries to voluntarily align with the ACO it will be clear to the ACO who their focus population is and to the beneficiary where they should first be seeking care. The expectation is that the closer relationship will engender a greater loyalty that will then reduce turn over from year to year in the population. A more stable population allows providers to better know and understand the needs of the beneficiaries and use this information to improve care.

We also believe that ACOs should be able to give members cards that they can carry that provide information about their ACO and coordinating physician office.

Very broadly, CHE Trinity Health believes that alignment of members (which can be advanced through opt-in) transforms practice for everyone, given that real investment needs to be made for a defined population. This is a person-centered practice – allowing a member to say "this is where I am getting care" – and moves the system away from a claims-based approach which was always intended to be a proxy for patient choice. We now have the ability to allow members to choose their care coordinator we should allow them to control the process.

Part B: Integrating Accountability for Medicare Part D Expenditures

1. **What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?**

   We strongly believe that reliance on PDPs will be an insufficient way for ACOs to integrate Part D spending into their accountability models. The distinction between medical benefits and pharmaceutical benefits is an historical artifact that unfortunately creates misalignment between the goals of PDPs and ACOs. In models like the ACO, encouraging medication adherence becomes an important tool in containing overall health costs, even as it increases drug spending. Conversely, PDPs are naturally encouraged to reduce drug spending. As a result, to make such a collaboration work successfully, ACOs and PDPs would need to carve out or make special allowances for adherence-dependent therapies.

   Integration of Part D expenditures also illustrates some of the challenges ACOs have with data timeliness. Since medication adherence is such an integral part of population health management, ACOs need to know about non-adherence quickly—far faster than a PDP could reasonably get such data to an ACO. Further, the high barriers for PDPs and ACOs in even identifying beneficiaries limit their ability to collaborate. We recommend that CMS and CMMI ease such barriers.

   Lastly, pharmacy risk assessment models differ from other risk models in that they do not distinguish between different levels of severity among enrollees who are prescribed drugs in the same therapy class. We recommend that these differences be taken into consideration so that risk adjustment methodologies used by PDPs are more accurate and aligned with those used by ACOs.

   A. **What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?**

      One stumbling block to considering strategies in this area is the inadequacies of the Part D data. There are challenges with the Part D data and how, or even if, it can be used given

that the paid amount is blank wherever it was provided through a Medicare Advantage plan. Given this limitation, ACOs would be at a disadvantage in approaching a Part D plan to establish a formal contractual relationship.

In addition, CHE Trinity Health recommends that CMS and CMMI facilitate meetings between representative PDPs and ACOs to develop solutions and best practices to sharing data and leveraging strengths for the most optimal patient outcomes.

2. **Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?**

   No

   A. **Why or why not?**

      Given the wide range of activities that an ACO, especially a fully capitated ACO, would be responsible for, we recommend that ACOs collaborate with PBMs rather than becoming a Part D sponsor or contracting directly with a PBM.

   B. **If ACOs assume accountability for Part D expenditures, what are the advantages/ disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?**

      The MSSP providers do not have experience with the Part D bidding process and thus would be at a distinct disadvantage. Moreover, meeting the state licensure requirements can be both costly and onerous, but it varies dramatically by state. In addition, it would be simpler for both CMS and the providers to have a unified MSSP program with a combined target for Parts A, B and D combined.

3. **Do ACOs currently have access to enough data to accept full risk for Part D expenditures?**

   No

   A. What other mechanisms would allow ACOs to assume accountability for Part D outcomes? For ACOs to assume accountability for Part D outcomes they would need to be able to obtain timely data on medication adherence, generic use rates, specialty drug use, refill rates, and drug costs. They would then need to be able to apply that information to a standing attributed beneficiary listing to be able to perform analysis on where savings could be realized and outcomes improved.

<u>Part C: Integrating Accountability for Medicaid Care Outcomes</u>

1. **Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?**

   Yes

A. Why or why not?

To the extent that ACOs can enter into similar arrangements across payers, the transformation will be faster and more effective. It is in the best interest of providers, CMS, states and beneficiaries to bring more populations into similar arrangements. However, this should not be compulsory as there is varying readiness among providers and states to move to such a model. Members report that even in states with state law authorizing Medicaid ACOs and state staff who are knowledgeable, the programs are very complex and getting buy in from the stakeholders and CMS challenging. There cannot be a one size fits all approach applied, so the implementation of joint Medicare/Medicaid ACOs will need to be state by state on a voluntary basis.

In addition, given that the State Innovation Models are currently underway, we recommend that CMS and CMMI look to successful models as guides.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes?

We believe the natural extension of the SSP ACO program and the dual demonstration models is to allow ACOs to become participants within the duals demonstrations. This is the population that would benefit the most from care coordination and coordination of the Medicaid and Medicare benefits.

While the aspiration of ACOs taking on a whole geographic area is admirable, we are very far removed from the possibility of doing that successfully in most markets. This would require unprecedented cooperation across providers, payers, the public health agencies, schools (depending on the population) and community-based organizations. We note that the population that may be the easiest to move to this even more comprehensive model is the disabled, but even with that population there is extensive ground work that would need to be completed with strong leadership from CMS before such a move. We think this is best pursued in the context of the State Innovation Models.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?

The states must play an integral role in aligning providers and payers. . Firstly, the states must ensure state law supports the models, which may not only require adding new authority under the Medicaid program, but also removing barriers in existing insurance and privacy laws as an example. In addition, the states must gain CMS approval through state plan amendments or other waivers. As part of these efforts, the states will be playing an active part in the design of the programs and what incentives are built in (as well as barriers removed) to encourage providers to enter into new payment models. This will not only benefit the Medicaid program, but the healthcare system more broadly. If CMS provides assistance to the states, it will serve to strengthen the Medicare program as well by allowing providers to more fully commit to the model and care transformation. Providing more SIM grants should facilitate the ability of more states to take this approach.

A. What roles should States play in supporting model design and implementation?

While we believe that States should be involved in model design to reflect the unique population served and care patterns in the area, the states are often ill equipped in terms of

expertise and capacity. To the extent that CMS could facilitate, the process might move faster. This could be in funds as well as technical assistance. For instance, the State Innovation Model grants have greatly facilitated states in developing alternative payment models that are advancing delivery system reform.

B. Do states have adequate resources to support an ACO initiative in collaboration with CMS?

Each state has a different level of expertise and resources to apply to such initiatives and this can be variable across time. Some states are moving ahead with very ambitious programs that we expect will be very successful. However, to ensure that pockets of the country are not left out of this transformation, CMS will need to provide significant assistance and resources to those that have not yet made significant progress.

In addition to providing states with grants and technical assistance to design new programs, CMS could also allow the Medicaid ACOs that may not be part of MSSP join the ACO Learning Network. CMS could also include a learning track geared to those ACOs that have taken responsibility for this population (whether in addition to Medicare or not). Another service CMS could provide to reduce the burden on states is to provide the data extracts to the providers. This would also ensure that the files are similarly constructed to the Medicare data making it easier for the ACOs to make use of the information. Finally CMS could also create a more extensive SIM learning system to accelerate the development of these capabilities at the state level. Ultimately the States have greater leverage to transform care delivery, particularly if CMS is an active partner.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?

CHE Trinity Health believes that CMS should work to standardize Medicaid data sets across states and develop a national Medicaid claims data system rapidly.

We also believe that the ACO programs should be changed such that all aligned Medicare and Medicaid beneficiary data is automatically provided to their aligned ACO and then simply provide an "opt out" option for beneficiaries who do not want their data to be shared.

A. What are the capabilities of providers in integrating this data with electronic health records?

NO RESPONSE

B. What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

NO RESPONSE

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures?

NO RESPONSE

Part D: Other Approaches for Increasing Accountability

1. **What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?**

   While we support the vision suggested by this question, we have such fundamental operational questions and concerns that it is difficult to comment concretely on this option. While there is merit in unifying the payment and quality policies for these currently distinct populations, this would fundamentally change the face of healthcare. Such a model would require not only health systems and community-based organizations to work together in a far more meaningful way, it would also require competing health systems to work with each other. While this is a laudable goal, it is difficult to conceive of upending the fundamental market dynamics in such a way in the near term.

   One particular population that has been discussed that could benefit from such an approach in the future is the disabled. Because this population receives such significant public funding from many different state and federal agencies, the need/urgency to move to such a model is greater. While the operational challenges would remain, there is an increased likelihood of getting disparate providers and other organizations coalesced around similar goals in the near term. We believe that the SIM pathway is the best way to move forward on this initiative.

   A. **What are the most critical design features of a provider-led community ACO model and why?**

   The return on investment would need to be clear through the structure of the model especially if the model includes risk. It would need to include protections to ensure that the providers/organizations that are contributing the most resources and achieving the most savings get commensurate shared savings.

   CHE Trinity Health believes that Medicare and Medicaid payment rates need to provide enough of a compelling reason to entice participants into the program. We think this can be accomplished by a greater share of the savings up front.

   B. **What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area?**

   NO RESPONSE

2. **Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?**

   Yes

   A. **More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments?**

   Yes

B. If so, what would the most critical features of such a "layered" ACO be and why?

We have encouraged CMS to include various service delivery and payment reform initiatives within the ACO program since its inception. While basing ACO payment on the fee-for-service system was necessary at the start of the program we believe it needs to evolve to further overcome the perverse incentives built into the existing system and shift compensation to supporting the Triple Aim™. For example, we think that medical home payments can serve to appropriately compensate primary care physicians for an increasingly prominent role in the continuum of care while still resulting in overall decreases in program expenditures. We also believe that bundled payment can play a critical role within an ACO and in fact a number of our members are in both the Medicare Shared Savings Program and the Bundled Payment for Care Improvement. Including bundled payments can, in particular, help to engage physician specialists who otherwise do not have enough return on investment to participate in ACOs.

Part E: Multi-Payer ACOs

1. **How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?**

   Conforming other payer contracts away from fee-for-service and toward models similar to the MSSP program is critical to the long-term success of the program. Consistency across contracts will result in faster and bolder results. Two stumbling blocks in this area include an unwillingness of some payers to share data, or only limited data, and the proliferation of quality measures. To the extent that CMS can assist in either of these areas, it would benefit not only Medicare but the healthcare system as a whole.

   In particular, CMS could develop a competitive program similar to the Comprehensive Primary Care Initiative where providers and payers apply together to enter into a coordinated effort to transform care with the government. However, this should also include grant funds that would be used on a local basis to work out agreements across all of the parties, including Medicare and potentially Medicaid, to implement a singular model of payment and quality measurement.

   In addition, CHE Trinity Health recommends a multi-payor model to be considered for integrated health systems with significant market contracting capabilities. To qualify, an integrated health system would need to have contracts with a large percentage of payors (approximately 80%). In this instance, CMS could initially share a large portion of the savings with the ACO partner (say 85%). This opportunity for large up-front savings could entice an integrated health system to participate more readily than a smaller savings sharing opportunity. The "Full Captitation- Equivalent Program" previously described could be used for these opportunities.

2. **How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?**
   CMS should work to consolidate measures in areas where many payers are willing to come together and agree to common methods.

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February 28, 2014

Centers of Medicare and Medicaid Services
Department of Health and Human Services

Re: **RFI: Evolution of ACO Initiative at CMS**

Thank you for the opportunity to provide comments on the Request for Information regarding the evolution of ACO initiatives at CMS. Cigna collaborates with health care professionals to achieve the triple aim – improved quality, affordability and patient satisfaction. We engage with physicians and health care professionals in multiple ways, through Cigna-HealthSpring's relationships with Independent Physician Associations (IPAs) and through Cigna's collaborative accountable care (CAC) program. We develop these engaged relationships based on aligned incentives, actionable information sharing, including health data and performance reports, and clinical resources to support care coordination and innovative health and wellness solutions. Additionally, we offer physician groups management support to help their practices operate more efficiently and effectively.

Well over one million Cigna and Cigna-HealthSpring customers benefit from 231 CAC programs in 31 states, with nearly 55,000 doctors participating, including nearly 19,000 primary care physicians and nearly 36,000 specialists.

Cigna is dedicated to improving outcomes and our physician engagement strategy is providing innovative solutions to health care challenges. These engaged relationships are transforming the health care experience through better adherence to evidence-based medicine guidelines and better rates for closing gaps in care. This better quality of care can result in better health for our customers and savings for our customers and clients.

Section 1: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

1. *Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?*

   As the direction of healthcare continues toward the concept of the "medical home" and integration, it appears that providers are increasingly considering the Pioneer ACO model as directionally appropriate. However, Cigna-HealthSpring has recommendations on how to modify this program for the upcoming round. We believe our recommendations will help the Pioneer ACO program maximize consumer choice and improve quality of care.

2. *If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?*

   CMS should accept all organizations that meet the qualifying criteria. If CMS is looking to increase the participation rate of the population served by Pioneer ACOs and encourage innovation, then

CMS should not restrict the participation base. Limiting the number of selected organizations will discourage new applicants in favor of more sophisticated ones. As a result, applicants will evaluate their own resources in light of their chances for success to determine whether to assign valuable resources to this initiative. To limit the selection process may also impact geographies differently, where CMS will have to define an appropriate number of participants per geography, which may ultimately not maximize beneficiary choice. In addition, CMS should allow providers as well as payors to participate in order to maximize the opportunities for innovation based on their varied and extensive experience.

3. *Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?*

As CMS continues to develop the Pioneer ACO Model, and moves participants towards accepting full risk, CMS should require that participants also demonstrate solvency and full insurance licensure, consistent with State regulations for the protection of consumers who utilize the ACO. CMS should reconsider the attribution model in favor of a predictive assignment methodology so that ACOs have better insight into the management of their populations. This will allow the ACOs to know in advance who the beneficiaries are that belong to their ACO, and be in a better position to manage their population, coordinate the delivery of health care services to them, track their health care expenditures, and better ensure the beneficiary's continuity of care, as well as provide the ability to facilitate an activated patient population. CMS should also consider implementing network requirements, with a clear distinction between in-network and out-of-network access, in order for health care organizations to better direct care to higher quality professionals who use evidenced-based medicine to improve outcomes for beneficiaries. CMS should also consider refining the definition of "performance" and "performance improvement" so entrants that are already high-performers have a continued opportunity to demonstrate their successes and tie these successes to financial performance throughout the demonstration's duration. This will encourage high-performers to continue innovating and improving health outcomes for the benefit of their beneficiaries.

CMS should simplify processes so that health care providers have capacity to work with Medicare ACOs well as other insurers. We are not aware of any major barriers other than organizational capacity to take on new initiatives and simplifying processes will result in increased consumer access to ACOs and improved quality of care.

In addition to streamlining processes, we also suggest a standardized or aligned approach to quality and cost measurement. CMS should continue to participate in national work groups that have been convened to focus on these issues and strongly encourage rapid progress. We would migrate in the direction determined by such work groups, as a single approach to patient alignment, quality measurement, and total medical cost measurement for commercial and CMS initiatives would help health care providers.

Population-Based Payments

1. *Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?*

If the intention of this program is to enable participants to effectively manage risk on behalf of their population, then participants should not be allowed to choose different FFS reduction amounts between the Part A and Part B services. The whole point of this navigation is for a participating health organization to fully harness risk and manage costs across the spend continuum, rather than to be selective. Selective efficiency is what organizations can deliver today, regardless of the Pioneer ACO model. Health organizations have different abilities to manage Part A costs versus Part B, but if they are going to innovate and participate in such a demonstration, then they should be

encouraged to make a commitment to be able to effectively manage both components in order to truly deliver cost savings to CMS and quality improvements to beneficiaries.

2. *Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?*

   No comment.

3. *Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?*

   Cigna-HealthSpring strongly encourages the adoption of clear requirements for financial reserves as a qualification to be a Pioneer ACO participant. Requesting a demonstration of savings in previous years is not a guarantee of future performance. If CMS is going to set up the participants for success rather than failure, and the participants are accepting full risk for their membership, then they must be fiscally sound.

4. *Should any additional refinements be made to the current Pioneer ACO PBP policy?*

   No comment.

Section II: Evolution of the ACO Model

Transition to Greater Insurance Risk

1. *Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?*

   While the notion of capitation with insurance risk is interesting, Cigna-HealthSpring is most concerned about the methodology that will be used to generate the potential capitation rates. It is critical that the capitation rates be calculated fairly to reflect the risk of the beneficiary being managed and the services to be provided by the ACO. To the extent the expectations for the ACO's role differ from those of a Medicare Advantage organization, it will be important for the capitation rate to be adjusted accordingly, so that neither model has a financial advantage over another. Additionally, it is important to note that a capitation will be difficult to be managed effectively by an ACO if they continue to receive beneficiaries through the attribution model. In order for a capitation to be meaningful, the ACO must be able to proactively view and manage their panel. Additionally, the ACO must have the ability to establish a network or at least be able to manage within the concept of in-network versus out-of-network. Network management provides a realistic opportunity for ACOs to be able to manage cost. If capitation is the direction that CMS would like to pursue, then Cigna-HealthSpring advises that participants meet financial reserve requirements and obtain relevant licensure within their service area states.

2. *What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)*

   To the extent full insurance risk is made available to participants, these ACOs should be responsible for all Medicare Parts. Furthermore, for certain participants that have membership heavily weighted in Medicaid, it is reasonable for them to also be responsible for Medicaid risk for dual-eligible beneficiaries. However, these participants should be required to establish a coordination agreement with state Medicaid departments and meet Medicaid requirements in order to be eligible to accept such risk. Considering the contracting burden that may be newly introduced to each state to support

this level of coordination, it may not be a reasonable expectation to allow participants to accept risk on Medicaid, particularly if they have no insurance licensure or ability to demonstrate financial solvency.

3. *Are there services that should be carved out of ACO capitation? Why?*

   To the extent that a participant accepts full risk, they should accept risk for all services that are currently covered by the Medicare program. Cigna-HealthSpring does not recommend that any services be carved out above and beyond the standard Medicare offering.

4. *What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?*

   No comment.

5. *What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would not be appropriate for ACOs assuming full insurance risk?*

   ACOs should be able to demonstrate financial solvency through capital reserve requirements and obtain insurance licensure through their service area states in order to assume full insurance risk. Aside from this, given the FFS environment, ACOs have minimal non-technological barriers to entry. To the extent in-network versus out-of-network constraints are developed for this program, which Cigna-HealthSpring strongly suggests, it would be advisable for ACOs to demonstrate referral patterns, document contracted networks, and meet network adequacy requirements.

6. *What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?*

   No comment.

7. *Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?*

   No comment.

8. *What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?*

   No comment.

9. *What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)*

   No comment.

10. *What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit*

enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

No comment.

11. *What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?*

    No comment.

12. *What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?*

    No comment.

13. *Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?*

    Cigna-HealthSpring believes that beneficiaries should be allowed to elect alignment to a Pioneer ACO even if they would not align through the attribution methodology. Ultimately the program is about beneficiary choice and an organization's ability to manage risk. To the extent a participant has foresight into their population, the participant will have greater ability to manage cost, creating incentives to better meet the needs of their members.

Integrating accountability for Medicare Part D Expenditures

1. *Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?*

   No comment.

2. *Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?*

   No comment.

3. *Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?*

   No comment.

Integrating accountability for Medicaid Care Outcomes

1. *CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?*

   Depending on the population being managed, participants should have just as much ability to affect Medicaid spend and outcomes as they do for Medicare. Based on management of their membership, participants should be allowed to accept risk for Medicaid performance. However, there should be consistency in this model, and therefore participants should be required to establish coordination agreements with each State. To the extent these agreements pose a contracting burden to a State, or are of interest to the State, the providers will encounter varying opportunities to accept risk by state.

2. *What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?*

   Participants should be accountable for outcomes of all Medicare-Medicaid beneficiaries, but not CHIP beneficiaries, unless it is specifically requested by the state. Participants should not be accountable for all beneficiaries residing in a specified geographic area, as there is no guarantee that the organization can affect the outcome of these individuals.

3. *What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?*

   No comment.

4. *What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?*

   No comment.

5. *What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?*

   No comment.

Other Approaches for Increasing Accountability

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1. *A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP*

beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

No comment.

2. *In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?*

   No comment.

Multi-Payer ACOs

1. *How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?*

   No comment.

2. *How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?*

   No comment.

CMMI RFI on Evolution of ACO Initiatives
Collaborative Health Systems (Universal American) Response – Section-by-Section
February 28, 2014

BACKGROUND

Organization Name: Collaborative Health Systems (CHS)
Point of Contact Name: Jeff Spight, SVP, ACO Market Operations
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Phone Number: 713.349.2249
Please select the option that best describes you.

- **Part of a Medicare ACO**
- Part of a Commercial ACO
- Part of both a Medicare ACO and a Commercial ACO
- Not part of a Medicare ACO or a Commercial ACO

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

Part A: Interest in Additional Pioneer ACOs

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model?
   Yes
   No
   A. Why or why not?

Collaborative Health Systems (CHS) and its parent company Universal American Corp. greatly appreciate the opportunity to submit feedback to CMMI on the evolution of ACO initiatives.

CHS is a managed services organization fully committed to the success of the Medicare Shared Savings Program (MSSP) and future ACO initiatives. Under our current model, CHS partners with primary care physicians (PCPs) and provides investment capital, care coordination services, technology and data analytics to improve the quality and cost effectiveness of care provided to Medicare beneficiaries. To date, CHS has created 35 MSSP ACO partnerships with leading PCP groups in 13 states. As of January 2014, we are working with approximately 4,000 physicians and 400,000 attributed beneficiaries under the MSSP.

We strongly believe that PCPs play the most important role in improving quality and appropriately managing the cost of care under Medicare fee-for service (FFS) ACO initiatives. PCPs must be positioned at the center of future ACO initiatives. They are best positioned to provide patient-centered treatment plans that focus on both the transitions of care (TOC) and chronic care coordination services that drive performance under ACO initiatives. Further, independent PCP practices operate free from the misaligned incentives of FFS that drive high Medicare utilization. With the incentive of shared savings under partial or full capitation, PCPs can serve as the key touch point for patients and allow CMS to expand ACO initiatives while maintaining beneficiary freedom of choice under Medicare FFS. We urge CMMI to maintain PCPs' ability to operate independently under future ACO models.

As discussed in our response to Section II.A.1., CHS supports gradually moving ACOs to full capitation risk. We view MSSP as a stepping stone to more advanced ACO models. However, at this point in time, it is premature for the majority of the CHS MSSP ACOs to transition into the Pioneer ACO program and we would not expect to apply to that model if the only opportunity to do so were immediate. Yet we remain interested in optional opportunities for MSSP ACOs to gain more experience with risk models on the path to full capitation risk. As our ACOs continue to develop capabilities and a greater capacity for managing risk with our PCP partners we would look to CMMI and CMS to create an accelerated risk model available for MSSP ACOs to enter, either through the Pioneer Model or a MSSP "Track 3" with similar characteristics.

Though few of our MSSP ACOs are presently prepared to assume Pioneer ACO level risk, there are key features of the Pioneer ACO model that would otherwise motivate them to apply. We urge CMS to incorporate the following Pioneer design elements into MSSP to drive continued development of existing ACOs:

- **Prospective attribution.** Prospective attribution would enable MSSP ACOs to better manage that population and empower them to take the appropriate steps to improve beneficiary engagement and identify and manage chronic conditions. Under retrospective attribution of MSSP, CHS ACOs have experienced 33% roster "churn" from quarter to quarter and this has undermined efforts to track progress on cost and quality during the performance period – which detracts from physician engagement.[1] We feel strongly that prospective attribution will improve on these figures. Though the medical practices engaged in our ACOs are committed to total transformation, it is an unlikely that all of an ACO's care management interventions could be applied to all Medicare beneficiaries seen by a provider regardless of whether such investments are ultimately linked to the ACO's financial reconciliation.

- **NPI-based attribution**. Building a successful ACO means partnering with providers fully committed to changing their practices to improve quality and manage cost. Often some practices within a larger system with a single tax identification number (TIN) are better prepared for this undertaking than others, and being able to build an aligned ACO population based on patients seen by these committed providers gives the ACO the greatest likelihood of success. The Pioneer ACO's NPI-based attribution model is ideal for this purpose. Though we understand that beneficiaries are aligned to the group of NPIs and not to individual providers, using NPI-level data during the attribution process makes it possible for CMS to deliver NPI encounter data to ACOs much earlier.

  Several key ACO operations flow from correctly identifying the physician NPI responsible for each beneficiary's primary care, including: (a) creating accurate provider-level utilization and outcome reports, (b) identifying appropriate physicians for quality measure collection and reporting, and (c) building consensus on shared savings distribution frameworks. Given the successful utilization of NPI-level data in the Pioneer ACO program, we trust that CMS has resolved the data infrastructure concerns expressed in the MSSP final rule as reasons for denying ACOs this important tool – in both structuring their organizations and more quickly linking patients and providers in care coordination relationships.

[1] Hoangmai H. Pham. Care Patterns in Medicare and Their Implications for Pay for Performance. *NEJM.* 2007.

- **Waiver of 3-day rule for SNF eligibility.** Medicare's requirement that skilled-nursing facility coverage be linked to a 3-day inpatient admission is a barrier to providing care in the most appropriate setting and drives unnecessary inpatient utilization. Since reducing unnecessary inpatient care is a key objective of the physician-based CHS ACOs, a waiver of this rule would be a powerful tool in improving care and lowering costs. Already available to other integrated models managing total cost of care – such as Medicare Advantage (MA), Pioneer ACOs, and PACE programs – this waiver should be extended to MSSP ACOs as well.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?
   --Limit the number of selected organizations
   --Accept all organizations that meet the qualifying criteria

   A. What are the advantages and/or disadvantages of either approach?
   [BLANK]

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?
   [BLANK]

Part B: Population-Based Payments for Pioneer ACOs

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP?
   Yes
   No

   A. Why or why not?
   [BLANK]

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?
   Yes
   No

   A. Why or why not?
   [BLANK]

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves?
   Yes
   No

   A. Why or why not?
   [BLANK]

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?
   Yes
   No

   A. Why or why not?

CHS believes the Pioneer ACO model is already testing the various iterations of population-based payments (PBPs) that are possible given the limitations of the concept as a mechanism to resolve one of the greatest needs of successful ACOs: ongoing access to capital to support care management infrastructure.

CHS believes PCP-based and physician-only ACOs represent the most effective model for improving quality and lowering cost under Medicare FFS. CHS' parent organization, Universal American Corp. (UAC), has extensive experience partnering with PCPs under capitation models and sharing net earnings under the Medicare Advantage (MA) plans that UAC plan sponsors manage. The full capitation payment under MA allows us to successfully administer these programs. We are concerned that setting PBPs as a required interim step before capitation payments could inadvertently disadvantage physician-only ACOs in the healthcare marketplace. Since PCP-led ACOs would only be eligible for a Part B-based PBP—and not the Part A-based PBP—they would continue to face significant financial limits in offering enhanced care management and other chronic condition disease management support and services. In addition, physician-based ACOs have less financial capital than large hospital systems or integrated providers, and a PBP policy does not reduce this disadvantage for such ACOs.

Under our typical ACO arrangement, Part B comprises a much smaller portion of total Medicare FFS spending compared to Part A. Since our ACOs are physician-based, this means the ACO fee-for-service (FFS) revenue only represents a smaller share of the total Part A and B spending for which it is accountable. **Table 1** below shows capital investment costs for CHS ACOs as a percent of the total Part A and B spending as well as the ACO-specific portion of Part B spending for attributed beneficiaries. While total investment only equals 1-2% of total Part A and B spend, the capital investment to start an ACO can range as high as 53% of our physician-only ACOs' annual Part B spend. In the context of PBPs, the physician-only ACO will be eligible for less partial-capitation while having a much greater need given the scale of investment costs.

Table 1. CHS MSSP ACO Capital Investment Compared to Total and ACO-Specific FFS Spending Amounts

	Bene Counts (Q2 2013 Roster)	Estimated FFS Spend (ITD thr 09/30/13)	FFS costs billed	Total ITD costs as a % of FFS spend	Total ITD costs as a % of ACO specific FFS spend	Total ITD costs as a pppm
Bene Cohort						
<10,000	114,919	1,406,603,790	44,413,138	1.31%	41.40%	10.93
>10,000 <20,000	155,805	1,442,436,550	76,324,329	1.33%	25.07%	10.84
> 20,000	47,584	650,707,580	13,767,509	1.12%	53.11%	10.92
	318,308	**3,499,747,921**	**134,504,977**	**1.28%**	**33.33%**	**10.89**
<7,500	38,307	378,238,865	13,898,962	1.53%	41.68%	11.10
>7,500 < 10,000	76,612	1,028,364,926	30,514,176	1.22%	41.27%	10.85
>10,000 <15,000	105,925	966,014,613	55,783,838	1.38%	23.89%	10.93
> 15,000	97,464	1,127,129,518	34,308,000	1.16%	38.22%	10.80
	318,308	**3,499,747,921**	**134,504,977**	**1.28%**	**33.33%**	**10.89**

While PBPs do offer some flexibility to pay physicians differently throughout the year (e.g., bonuses for conducting health risk assessments, IT project improvement), this current proposal unfairly favors hospitals. Yet, PBPs could represent a useful tool to orient physicians away from volume and to work ACOs up towards taking on transient populations. However, this does not outweigh our concerns should PBPs proliferate, hospital-based ACOs will become more attractive and the overall ACO market could shift away from the vital physician-only ACO model.

SECTION II: Evolution of the ACO Model

Part A: Transition to Greater Insurance Risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations?
   Yes
   No

   A. What are the potential benefits and risks to the Medicare program and beneficiaries?

Working with 35 physician-based MSSP ACOs, CHS supports the prospect of moving the ACO model to full capitation. As previously stated, we believe that PCP and physician-based ACOs represent the most important and effective model for improving quality and reducing cost under Medicare FFS. Our conviction is driven by over 15 years of success partnering with independent PCP practices under our Medicare Advantage (MA) health plans. Without capitation, the only ACOs with enough capital reserves and financial flexibility to invest in the technology infrastructure, staffing and care management programs necessary to drive success will be those who partner with hospitals.

For the PCP model to succeed, CMS will need to give ACOs, operating under capitation, the tools to improve quality care and lower costs for Medicare beneficiaries. ACO capitation will differ from MA if CMS keeps current ACO claims-based attribution rules and beneficiary freedom of choice in Medicare

FFS. These rules allow ACOs to bring the benefits of care coordination to Medicare FFS beneficiaries without adding the marketing and enrollments costs of Medicare Advantage plans into the health care system. To attract ACO participants and position them for success under capitation, CMS must balance the objectives of beneficiary freedom of choice in FFS with policies that will allow the ACO to effectively manage medical risk and reduce unnecessary utilization. We urge CMMI to consider the following suggestions when crafting future ACO capitation program design:

- **Maintain ACO claims-based beneficiary attribution.** Claims-based prospective attribution, coupled with an opt-in option for non-attributed members, provides ACOs with meaningful financial incentives to improve care for the population of patients with whom they already have care relationships. The ease and economic benefit of the ACO model's automatic attribution of beneficiaries is a key component of an ACO capitation program's attractiveness.

- **Provide ACOs with more comprehensive, market-level Medicare claims data.** ACOs can manage risk under capitation if they put actionable and comprehensive data in the hands of the PCP. The data-driven insights may include physician-level reporting on attributed beneficiaries' cost and utilization trends, as well as episode-type group (ETG) analytics to assess the cost and quality of specialists, hospitals, and post-acute care (PAC) providers. Numerous health IT and analytics vendors offer referral intelligence tools and algorithms that transform longitudinal claims data into provider-specific ETG profiles. These are powerful tools in the hands of a physician with shared savings incentives under a capitated contract. With data, ACOs can build virtual networks based on data-driven insights on which providers are the highest quality and lowest cost. Though beneficiaries would maintain the freedom to seek care anywhere, this powerful data analysis would be an invaluable tool for ACO physicians to encourage patients to make care choices based on quality outcomes.

- **Empower ACOs to incentivize providers and patients to improve care inside Medicare FFS.** Under capitation, ACOs can implement reimbursement systems that incorporate and incentivize new services and technologies that focus on efficiency, prevention and primary care. One of the primary advantages of capitation is that ACOs could pay providers differently. CMS should provide capitated ACOs more freedom in the types of tools and services they deliver to their patients. This includes more flexibility in reimbursement policy so that physicians, home health agencies, and other providers (e.g., nurse practitioners) can be reimbursed for remote monitoring, telehealth, and email consults with patients and their families that are related to a Part B provider service. Such "virtual' encounters should receive payment; they are efficient means of care delivery for many patients, and they can be used to aid in the attribution of patients to the ACO.

  Central to the concept of the ACO is the ability to maintain the patient in the community. Technology advancements in recent years have made such "virtual" consults much more applicable and valuable to population-health models. This type of flexibility will require additions to the current Medicare fee schedules, and we encourage CMS and CMMI, as they think through the evolution of the ACO model, to consider explicitly a broad, flexible framework for ACOs to reimburse providers for such technology enabled services. CMS must also consider how capitation arrangements that change the flow of FFS claims to Medicare should be organized in such a way that ACOs using innovative technologies to manage patient populations wouldn't be disadvantaged in future years' attribution because they are a replacement for office visits.

- **Higher benchmark than MA counterparts.** Even with lower regulatory burden and improved data, ACOs operating under capitation and dealing with beneficiary freedom of choice under FFS have fewer tools to manage risk than their MA counterparts. Without a narrow network or differential pricing among providers, ACOs will have a limited ability to predict the proportion of care that will be delivered to its aligned providers, and the portion it will pay out externally in claims. The unknown magnitude of this "leakage" will require either conservative investments in care coordination initiatives or additional resources. CMS should account for this disadvantage in setting the benchmark for ACOs and ensure regulatory neutrality and fairness in the marketplace.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

We believe CMMI should allow ACOs operating under capitation to be responsible for Part A, B, D, and certain Medicaid risks. Separating medical care from pharmacy is an artifact of history – ideally no provider would separate prescription drug data from the management of the rest of the patient care. ACOs will succeed under capitation if they can effectively manage the maximum number of services. CHS strongly supports a fully integrated approach to risk management, including all spending under Parts A, B and D of the Medicare program. The role of outpatient prescription drugs and infusion therapies is central to the ability of risk bearers to manage the health of individuals who have been prescribed maintenance drugs and drugs for chronic conditions. Inconsistent adherence to such medication regimes is one of the major challenges in managing such risk successfully.

In order to manage patient health successfully, ACOs will need to have transparency into how patients adhere – or fail to adhere – to these programs. This will require them to work closely with pharmacies as well as Part D plans to have real-time information available to identify any need for interventions. Such collaboration will require ACOs and Part D plans to establish separate models for ensuring that each entity finds value. The division of medical and pharmaceutical benefits creates an artificial distinction in payment that fails to reflect the reality of effective coordinated healthcare; in some cases, Part D spending should rise in order to reduce overall healthcare spending, but such incentives are misaligned in the current Medicare payment environment.

We also believe that CMMI and CMS should strongly consider the integration of long-stay nursing home Medicaid beneficiaries into the ACO model. As we note in section C, such long-stay patients represent abnormally high risk for hospital admissions and readmissions, and integration of such patients into the ACO model will serve as a catalyst for ACOs to develop and implement much greater alignment between physicians and skilled nursing facilities. Moreover, it directly addresses one of the most expensive elements of State Medicaid programs and will facilitate a greater emphasis on patient well-being within the nursing home. Finally, integration of long-stay residents into the patient care programs that ACOs are developing will effectively integrate the dual eligible populations in those communities – a population that represents substantial insurance risk. We elaborate on this recommendation in Section C.

There are significant challenges with developing accountable care models around the Medicaid population. We acknowledge these challenges. But without an explicit focus that the ACO model provides, we will miss a golden opportunity to extend this promising model to some of the most vulnerable and expensive populations.

3. Are there services that should be carved out of ACO capitation? Why?

Certain services should be carved out of the calculations used to establish spending baselines and savings targets. CHS strongly suggests that end-stage renal disease patients, organ transplant patients, hospice, and patients that incur more than $100,000 in annual Medicare reimbursement should be excluded from these ACO calculations.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

In order to manage capitation risk successfully, the ACO will need working relationships with hospitals, pharmacies, skilled nursing facilities, and other post-acute care (PAC) providers. In particular, the current absence of daily discharge and census reports from hospitals, outside of the ACO boundaries, hinders ACOs implementing transition of care (TOC) coordination services. We believe CMS must work to address this data gap if ACOs – particularly physician-based ACOs – are to manage full capitation risk. This could either be accomplished through CMS's own data infrastructure – relaying beneficiary eligibility validations from hospitals in real time to the ACO – or by finding a policy solution that enables and requires hospitals to comply with certain, defined ACO real-time data needs for the benefit of Medicare patients. Meanwhile, pharmacies, skilled nursing and other PAC providers are essential to the successful management of therapy, rehabilitation, and return to health.

We also believe that ACOs need the ability to transact patient information directly with retail pharmacies – bypassing Part D plans – to ensure that patients on medication adherence programs remain on such programs for the duration of the prescribed therapy.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk?

We believe that certain benefit restrictions should be waived for ACO participants. For example, in Section 1.A.1 we mention waiving the 3-day hospital stay requirement prior to a SNF admit. Under the current MSSP ACO structures, patients must still have a three-day hospital stay before being eligible for Medicare-covered stays in skilled-nursing facilities. Direct admission to SNFs leaves patients exposed to significant out-of-pocket expenses, yet many inpatient hospital stays are purely observational in nature and could be done in a lower-cost setting that demonstrates strong physician presence. Waiving the three-day hospital stay requirement would allow physicians to optimize where patients receive care while protecting beneficiary out-of-pocket costs.

Similar to MA plans, ACOs should have wide discretion to modify or eliminate restrictions on benefits or services for attributed beneficiaries. We support the removal of restrictions on physician decision-making with regard to appropriate sites of care, particularly with regard to patients requiring observation care.

In the framework of the ACO-risk model, the regulatory and compliance elements must allow for sufficient care management programs to manage the additional risk and provider claims payment, yet retain the open-access, freedom of choice, the beneficiaries currently have in Medicare FFS. We would

recommend the following as consideration in the ACO-risk model that would strengthen the care delivered to the ACO beneficiary, and still differentiate the ACO model from the MA Program:

- The ACO model should, at the very least, allow for supplemental benefits and benefit modifications. We would also be interested in exploring modeling flexibility in the hospital benefit periods. And consideration should be given to an ACO-level deductible and cost-share that would encourage better provider-patient engagement without the out-of-pocket constraints of the traditional Medicare program. CMS and CMMI also could consider tiering patient cost-sharing based on a beneficiary accessing and receiving services from their ACO provider versus a non-ACO provider. This would be similar to the modeling that MA Plans now have in their Bid development.

- In order to manage the capitation, the ACO, in its fee-for-service payments to providers who are aligned with the ACO, should have flexibility to establish fee schedules that would not duplicate the Medicare physician fee schedule, but instead provides incentives to the caregivers who are the primary drivers of the healthy outcomes of the ACO beneficiaries. This could, in some instances and at the discretion of the ACO, include sub-capitation to providers such as DME, physical therapy and similar medical sub-specialties who receive ACO beneficiaries on a referral type basis.

- There should not be a dedicated enrollment function, as in the MA Program. That would place administrative burdens on the ACO and would be a distraction to the beneficiary who might feel restricted. At the same time, the ability to manage the ACO-risk model in this open-access model is predicated on aligning providers and patients along with the acuity of the beneficiary ACO population. As mentioned elsewhere in this response, there needs to be prospective assignment of beneficiaries from year to year. Under risk-based capitation, the ACO would have much more incentive to get the ACO beneficiaries into the office and under a care program, i.e., manage each to as healthy an outcome as possible to maximize the capitation revenue.

- The ACO should be responsible for provider disputes when the payment issue is an ACO responsibility but the ACO should not be functionally responsible for member appeals and grievances, similar to the MA Program that has a dedicated enrollee population. The ACO beneficiary issues should continue to be administered as they are now under the traditional Medicare program.

Since the ACO is an open-access model, it remains an open fee-for-service model. In such a model, the ACO should not have responsibility for any documented network adequacy oversight and/or minimum acute hospital beds. The ACO would pay Medicare FFS reimbursement rates for traditional Part A and Part B services provided to ACO patients by non-ACO providers.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities?
   [BLANK]

   What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

We refer to our answer in II.A.5.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

ACOs operating under capitation would need to develop new capabilities or contracts with vendors to perform more complex data analysis, non-ACO provider communication and outreach, claims processing, and beneficiary engagement. Specifically, ACOs would require:

- Actuarial capabilities
- Fund management capabilities
- Grievance and appeal capabilities for those payments and services for which the ACO is fully responsible
- Health coaching capabilities
- New contracting functions
- New rules engines around claims payment and analytics

8. The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are approaches for setting appropriate capitation rates?

The current blend of national and local benchmarks should be replaced with ACO-specific benchmarks. Local market factors far outweigh national factors in determining overall healthcare resource utilization. However, CMS should explore ways to ensure that high performing ACOs are not unfairly penalized with low benchmark levels based on historical spend. The population focus of the ACO model should use that population as the primary independent variable in determining whether an ACO has made progress against per capita spending targets.

A. What are the advantages and disadvantages of using national expenditure growth trends?
[BLANK]

B. What about for using a local reference expenditure growth trend instead?
[BLANK]

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)
[BLANK]

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes?

To encourage beneficiary engagement, self-management, and the receiving of care from ACO providers, CHS supports making certain benefit enhancements available. We recommend that CMS allow providers more flexibility in the types of financial incentives and benefit enhancements that ACOs may use to encourage beneficiary engagement with ACO primary care physicians and care coordinators. These incentives could include some of the tools currently available to MA plans, such as reduced cost-sharing and value-added benefits and some coverage for non-Medicare mandated benefits like vision

care and dental services. Alternatively, CMS could permit ACOs to offer targeted financial benefits for positive behaviors, such as medication adherence, or for high-risk, high cost beneficiaries who are compliant with a comprehensive care management plan.

In our experience with MA plans and across our 35 MSSP ACOs, transportation services and additional support for social workers and/or health aides represent a critical element of successful care coordination programs. ACOs operate under an expanded and flexible benefit structure that allows them the option to pay for services, such as transportation for low income seniors and care coordination services during transitions of care, that will drive improvement in the quality and total cost of care. The flexibility afforded through capitated payments would further enhance ACOs' ability to make these investments.

CMS should also explore allowing ACOs to sell their own "gap" coverage targeted to the ACO network and special clinical needs of the membership. Seniors that need access to improved benefits should have a different kind of Medigap coverage available to them that allows the ACO to address directly cost-sharing.

A. How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

In Section C, we address in detail how existing benefits within the Medicaid program need to be integrated into a joint Medicare/Medicaid ACO model, particularly with respect to nursing home care.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?
[BLANK]

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?
[BLANK]

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology?
Yes
No

A. What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

CHS is fully committed to the ACO model as a claims-based attribution model and considers this a key distinction between the ACO model and Medicare Advantage – allowing ACOs to focus on improving care coordination and health outcomes, and not on marketing. However, CHS supports adding beneficiary attestation into an ACO as a supplemental form of alignment so that patients with loyal

relationships to ACO practices may see the enhanced benefits of care coordination investments even if they are left out by the quirks of claims-based attribution. Allowing beneficiaries to elect into the ACO will also allow physician groups to more fully transform their practices, by including more of their patients and achieving the scale necessary for such population health models to work. Moreover, more beneficiaries will have the choice to align with a model that expressly focuses on primary and preventive care, which would be empowering and engaging.

In addition, ACOs that are forced to compete for voluntary patient alignment will have every incentive to demonstrate clear quality gains and articulate precisely why alignment with an ACO is in the patient's best interest. One of the challenges noted by the early adopters of the ACO model is the high percentage of care that patients seek outside defined ACO participants. Though the burden is on the ACO to encourage patients to seek care from its participants, the addition of voluntary beneficiary alignment will not only increase the premium on their ability to communicate the value of in-ACO care, but should also stir innovation in the way care is designed.

Part B: Integrating Accountability for Medicare Part D Expenditures

1. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?

The biggest problem right now is that even a large PDP is only helpful for just a portion of total ACO lives. The mismatch between the broader ACO patient population and any given PDP is a pronounced barrier to effective collaboration. Right now, ACOs and PDPs are striking narrow deals (if striking a deal at all) as a way to start somewhere and build relationships.

A current example of such a collaboration offered in the market is a construct in which the ACO physicians get their attributed patients to sign up for the PDP, while giving the ACO upside on the PDP risk. While PDPs have not sought a portion of the ACO savings directly, some have tried to lure ACOs into deals by giving them access to profits under the Part D capitation. In some cases they'll split PDP savings 50/50 on the ACO lives. The PDP sees little downside to this arrangement, viewing it as a growth opportunity. The PDP and ACO set a pharmacy budget together to create a benchmark and then work together to lower MLR and cut drug costs. As part of the deal, the PDP also provides weekly data on medication through an online platform – a critical need for ACOs in obtaining timely data.

But this is where the incentives between the two parties diverge. Medication adherence is treated differently because it adds to total medication costs. In the aforementioned ACO-PDP partnership, the PDP will carve out any adherence-specific extras from the above gainshare and charges a fee.

Ultimately, ACOs need to know about prescription drug problems, especially non adherence, very quickly. The claims lag hurts an ACO's ability to implement effective interventions. Integrating accountability improves the effectiveness of medication management programs – for example, CHS ACOs use prescription drug data in risk stratification, case identification and then many types of remediation programs. Given the challenges with ACO-PDP partnerships under current rules, and the importance of integrating prescription drug data with larger clinical and medical histories, we strongly urge CMS to consider innovative approaches to integrating Part D spending with Part A and Part B under the ACO.

A. What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

ACO providers have little to no control over Part D expenditures, and Part D plans have little if any incentive to want to collaborate. Part D plans also have little to no incentive to reduce spending outside of prescription drugs, whereas ACOs aim to decrease overall spending while retaining or improving quality. If CMS integrated Part D spending into the benchmark and performance calculations, CMS would need to restructure and align the incentives between Part D plans and ACOs. In addition, providers would require real-time data from PDPs and complete access to Part D claims information from CMS.

Real-time Part D claims information would empower providers to identify areas where spending could be decreased in addition to informing providers as they evaluate opportunities to collaborate with specific Part D plans. It would also improve the effectiveness of ACO medical management programs, as CHS could use prescription drug data to inform risk stratification, case identification and subsequent intervention programs.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?
   Yes
   No

   A. Why or why not?

Please see response to Section II - Part B – Questions 1A.

   B. If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?
   [BLANK]

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures?
   Yes
   No

ACOs need to know about prescription drug problems, especially non adherence, in real time. The claims lag would hinder the ACOs' ability to implement effective interventions. Integrating accountability improves the effectiveness of medication management programs – for example, CHS ACOs use prescription drug data in risk stratification, case identification and then many types of remediation programs.

   A. What other mechanisms would allow ACOs to assume accountability for Part D outcomes?
   [BLANK]

Part C: Integrating Accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?
   Yes
   No

Medicare ACOs should assume accountability for Medicaid outcomes for the dually eligible beneficiaries aligned to their ACOs, to the extent that ACOs can effectively manage those outcomes. Given the complexity of most State's Medicaid programs, this likely would result in making ACOs accountable for certain, but not all, Medicaid outcomes. When considering a national policy that would enable Medicare ACOs to assume responsibility for some Medicaid outcomes for dual eligible beneficiaries, two areas appear particularly appropriate. First, ACOs should be accountable for Medicaid's cost sharing for Medicare-covered services. To the extent ACOs effectively manage the Medicare services, the associated savings benefit should accrue not just to CMS and the State, but to the ACO as well.

Second, CMS should consider making ACOs accountable for Medicaid nursing facility (NF) outcomes. The Medicaid-to-Medicare cost shifting incentives associated with NF care are well known; estimates of the number of hospital admissions coming from NFs that are potentially avoidable range from 30% to more than 60%. And while no single cause for this high rate exists, misaligned financial incentives likely play a key role. These hospitalizations are expensive, disruptive, and disorienting, and unnecessarily leave NF residents vulnerable to the risks that accompany hospital stays and transitions between NFs and hospitals

A NF-based ACO would operate alongside an existing Medicare ACO, not as a fully new program but as a way of allowing for existing ACOs to share in certain Medicaid savings. A NF-based ACO model would build on the experiences and care coordination investments of the existing ACO programs, particularly by helping to align incentives between NFs and primary care providers. The savings generated by the ACOs also would allow for reinvestment in care provided at and by the NFs. Noting the importance of addressing the misaligned NF-hospital incentive, CMS already has developed several initiatives designed to reduce the hospitalization of NF patients. Most notably, the Medicare Advantage Institutional Special Needs Plan (ISNP) model provides evidence of the effectiveness of models like this. Other programs include the Nursing Home Value-Based Purchasing Demonstration and the Initiative to Reduce Avoidable Hospitalizations among Nursing Facility Residents.

A NF-based ACO could offer a new targeted model that builds on the Medicare ACO program and provides an opportunity to integrate Medicare and Medicaid costs and outcomes. Although State Medicaid programs differ significantly from one another, States consistently cover long-term NF stays for 65+ dual population. Accordingly, this model could be rolled out across multiple States with limited administrative complexity. In addition, the incentives of this model align with Medicare ACOs, and particularly, CHS's ACOs. All of our ACOs are provider driven, free of underlying incentives to maintain a certain level of hospital admissions. In the same way that our ACOs are incentivized to avoid hospitalization to the extent not necessary, the same incentive exists with respect to long term NF residents and the providers managing and providing their care.

Finally, ACOs are well positioned to be held accountable for Medicare and Medicaid outcomes specifically for NF residents because, in contrast to many other populations, ACOs have the ability to impact all care that is provided to this population. We believe this tenet – making ACOs accountable solely for outcomes that they have the ability to impact – should underlie any ACO model and explains why we do not believe that Medicare ACOs can be held accountable for Medicaid services provided to beneficiaries residing in the community. Medicaid home and community-based services (HCBS) are provided through waiver programs and managed by states, localities, or managed long term care programs. Medicaid behavioral health services are far more extensive than those covered by Medicare. In both cases, Medicare ACOs do not have the infrastructure and resources to manage these services and in some cases, may not have the authority. If the ACO cannot impact the care and outcomes for a group of services, we do not believe that they should be held accountable for those services.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

As described in response to Section C.1, CMS should prioritize integrating accountability for dual eligibles who reside in nursing facilities where they are receiving custodial long term care services. To do so effectively, CMS may have to reconsider its attribution methodology for this population. Given that these beneficiaries reside in the nursing facility and likely receive little outpatient care from community providers, CMS would have to consider an attribution methodology that effectively aligns the nursing facility population to the particular ACO with the most effective care coordination infrastructure for that community. One solution may be requiring that ACOs enter exclusive agreements nursing facilities, then making the ACO responsible for the entire dual population in each particular nursing facility. This model would likely need to exclude States or select counties within States that are implementing Financial Alignment Demonstrations that include custodial long term care, states with Medicaid managed long term care programs that include custodial long term care, and nursing facilities that contract with ISNPs.

3. (3A, 3B) What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

States would have to play an integral role in developing an integrated nursing facility ACO model. Data held by the state about utilization and quality of nursing homes would be essential to ACOs seeking to create those partnerships and investments. Further, States would need to participate in developing the shared savings model that would allow ACOs to share in a portion of the savings that would otherwise accrue solely to the State and CMS through reduced Medicaid spending. Because CHS operates ACOs in 13 different states, we would hope that these efforts would not occur in isolation but that CMS would establish a strong framework for states to sign onto, clear guidance about possible changes needed in state financing and regulatory frameworks in order to make shared savings possible, and robust resources to support State data infrastructure to meet the needs of ACOs.

4. (4A, 4B) What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?
   [BLANK]

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

As described in response to Question 1, careful considering needs to be given to the Medicaid expenditures that ACOs would be held accountable for. The only Medicaid risk that should be assumed is that risk that can be effectively managed by the ACO. To the extent a dual enrollee receives services that cannot be managed by an ACO (e.g. waiver services), the ACO should not be accountable.

Part D: Other Approaches for Increasing Accountability

1. (1, 1A, 1B, 1C) What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?
   [BLANK]

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?
   Yes
   No

   A. More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments.
      Yes
      No

   B. If so, what would the most critical features of such a "layered" ACO be and why?

As described in Section II, CHS supports the development of an ACO model with fully capitated risk and payments and believes that such a model could include a variety of payment arrangements with individual providers within it. Noting the value in episodic based payments, such as those used in the Bundled Payments for Care Improvement initiative (BPCI), in reducing variation in cost and quality for acute care episodes, CHS would expect to engage directly with BPCI participants and pay participants in that program directly from the ACO's capitation arrangement. This type of payment arrangement, especially with providers outside of the ACO, would require direct facilitation by CMS – allowing the

capitated ACO to pay non-ACO providers via methodologies (such as bundled payments) beyond the traditional FFS schedule.

Part E: Multi-Payer ACOs

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RESPONSE TO CMMI REQUEST FOR INFORMATION
REGARDING
THE EVOLUTION OF ACO INITIATIVES AT CMS

John S. Cook
Jack C. Keane
Robert B. Murray

2/27/2014

The purpose of these comments is to provide CMS with our observations regarding various aspects of the Shared Savings Program Accountable Care Organization (SSP ACO) and the Pioneer ACO programs that we believe have the effect of (a) severely limiting the potential of these programs to generate significant savings for Medicare; and (b) sharply curtailing the extent to which these programs can serve as vehicles to move the health care system along the path set out in the Three Part Aim that has been set forth by CMS.

We recognize that the format of these comments does not conform precisely to the template provided in the Request for Information (RFI) issued by CMS. However, we hope that these comments will be considered on the basis of their substantive merits rather than on the basis of their compliance with the format prescribed in the RFI.

A. Background

In 2011, the Center for Medicare and Medicaid Innovation (CMMI) launched the Pioneer ACO Program by selecting 32 provider groups to participate in the first round of this initiative. The program aligns Medicare beneficiaries with each ACO, establishes annual target budgets for the aligned beneficiaries, specifies a series of quality metrics to assess the quality of care provided by the ACO, and makes the ACO accountable for the costs and quality of care provided to these beneficiaries through risk sharing arrangements.

An initial evaluation of the first year results of the Pioneer program showed that the cost control performance of this initial group of Pioneer ACO participants was lackluster. Only 18 of the 32 ACOs had a target budget surplus; only 13 exceeded the minimum savings rate (MSR) threshold in order to be eligible for incentive payments; Part A and Part B claims per aligned beneficiaries increased .3%, or 0.5% below the U.S. average for a comparable group of beneficiaries; and 9 of the 32 ACOs dropped out of the program at the end of the year. Subsequent evaluations of the Pioneer ACO program have found slightly more favorable performance, but the results remain disappointing.

This unimpressive cost control performance does not account for the fact that most ACOs incur substantial infrastructure and administrative expenses that are not reimbursable by Medicare. These costs typically exceed the average reduction in Medicare claims expenses that

was achieved by the Pioneer ACOs. Therefore, if we account for the total Medicare-related expenditures of the Pioneer ACOs—including their Part A and Part B claims, infrastructure investments and administrative expenses—they can rightly be viewed as having produced no sustainable cost reductions even though they were chosen from among the leading managed care-oriented provider groups in the U.S.

We believe that the weak cost control performance of the Pioneer ACOs (and the SSP ACOs) is directly traceable to several basic design features of the programs which could be partially or wholly corrected by CMS.

B. Historical Precedents

The weak cost control results that have been produced by the Pioneer ACOs (and by the SSP ACOs) are not without historical precedent. The Physician Group Practice (PGP) demonstration was the first "pay for performance" Medicare initiative. It involved ten carefully selected multi-specialty physician groups (including two entities affiliated with Academic Medical Centers). Most of the selected groups had strong hospital affiliation or ownership links. The PGP program aligned Medicare beneficiaries with each PGP group; it established annual target budgets for the aligned beneficiaries over a five-year period beginning 4/1/2005; and it shared savings with groups that achieved at least a "Minimum Savings Rate" (MSR) in their target budgets. Only two of the PGP groups realized consistent savings and only one (the Marshfield Clinic) realized substantial savings—in fact, it accounted for more than half of the total savings generated under the PGP program. The Marshfield Clinic's savings appear to have been at least partly attributable to improved clinical coding practices that raised the measured severity of illness of its aligned beneficiaries and yielded proportional increases in the related target budgets and in the associated savings.

The PGP program's independent evaluator referred to the savings that it produced as "small" and "extremely variable" (the savings ranged from a few hundred thousand dollars to over $16 million) with only four of the 10 groups qualifying for shared savings (which totaled only $29.4 million) in the fifth and final year. In addition to the small savings produced, the evaluator raised doubts about the extent to which the PGP groups generated savings by actually reduced spending or generated ersatz savings by up-coding the diagnoses and severity levels of Medicare patients included in the demonstration. (If the illness severity of the beneficiaries covered by the PGP groups under the program had increased at the same rate as severity levels in the same geographic area, rather than at a higher rate, only one PGP group would have qualified for bonuses). The evaluators of the PGP were not able to link savings to specific interventions and found that the formal programs the PGP sites adopted were directed at very small patient sub-populations. The groups did not attempt to reorganize the basic care which they provided or arranged for all patients.[1]

[1] Berenson, R. and Burton, R.A. Accountable Care Organizations in Medicare and the Private Sector: A Status Update. November, 2011. The Urban Institute. Washington DC

The underwhelming cost control performance that was reported for the PGP groups is consistent with the results of other ACO-type incentive arrangements that have involved hospitals as core participants —e.g., the "Alternative Quality Contract" (AQC) incentive arrangement that was implemented during the last several years by Blue Cross Blue Shield (BCBS) of Massachusetts. Moreover, the minor savings that were produced by the PGP groups did not account for the infrastructure and administrative expenditures they incurred under the PGP program. If these costs were recognized and counted against the savings, it is likely that the PGP groups produced no significant reductions in the costs of providing care to their aligned beneficiaries, notwithstanding the performance of the Marshfield Clinic.

C. The Importance of PCPs and the Anti-PCP Risk Features of the Pioneer and SSP ACOs

A large proportion of the Pioneer ACOs (and their SSP ACO counterparts) are organized by hospitals or are based on "health systems" that include a broad spectrum of providers including hospitals, specialists, and other providers. As we will explain below, hospitals (and specialists) have financial interests that are generally inconsistent with the cost control objectives of the ACO programs. In particular, hospitals have fixed cost levels that make volume reductions, which are the main keys to meaningful PMPM-based cost control, highly unattractive from a financial perspective. It is entirely predictable that ACOs that include hospitals as core participants will not engage in the volume-reducing behaviors that would lead to significant cost reductions. Procedure-oriented specialists also do not view reductions in the frequency of unnecessary tests and procedures as consistent with their financial interests given the savings sharing percentages that are available in an ACO structure.

Unfortunately, the risk levels that are imposed on the ACOs (initially or within a few years) create a de-facto organizational requirement that ACOs involve hospitals (and specialists) with substantial financial reserves as core participants. This feature effectively prevents primary care physicians (PCPs) from establishing ACOs in which they would assume the leading role that they can and should play in directing care and managing costs. Instead, PCPs become enmeshed in organizational structures and incentive systems dictated by hospitals and health systems. These arrangements are usually designed, deliberately or by unconscious self-interest, to thwart any actions that would seriously threaten the financial interests of the participating hospitals and specialists. We believe that PCPs, if they were not shackled to ACO risk requirements that dictate that they must have hospital and specialist, could be strong forces in support of improved access, greater affordability and better quality.

We believe that PCPs should be placed at the center of ACO programs, for operational rather than merely alignment purposes, for a number of compelling reasons.

- First, PCPs can provide their aligned beneficiaries with much-needed primary care including the care coordination services that are generally lacking in today's health care system. This lack of care management is especially inadequate for elderly persons with multiple health problems.

- Second, primary care services are generally undersupplied in the current health care environment. Therefore, in contrast with hospitals and specialists, PCPs do not fear volume reductions and the revenue reductions that usually come with them. PCPs know that effective ACOs will require more, not less, primary care. Finally, PCPs are generally underpaid, and many health services researchers and policy experts believe that increasing their incomes is an important prerequisite for ensuring an adequate base of primary care services in the future.

- Finally, it is possible to provide PCPs with large income improvements by giving them a relatively small share of total cost savings. PCPs can be powerfully motivated, at an affordable cost, to pursue cost reductions and other aspects of the Three Part Aim, whereas it is very difficult to offer hospitals (and specialists) financial rewards that are sufficient to motivate them to make significant changes in their engrained fee-for-service (FFS) practices.

1. The Role of PCPs in the Pioneer and SSP ACO Programs

The rules governing the "alignment" of Medicare beneficiaries with an ACO establish a central role for the ACO's PCPs in identifying the beneficiaries who will be encompassed by the ACO. Specifically, nearly all Medicare beneficiaries who are aligned with an ACO are aligned based on the finding that a PCP included on the provider roster of the ACO provided the plurality of the beneficiary's primary care E&M services as measured by allowed charges during a specified alignment period. However, the Pioneer risk arrangement places too much risk on an ACO to allow a group of PCPs to sensibly enter into an ACO arrangement without the backing of an organization with substantial financial resources. Thus, with some rare exceptions, PCP-led groups (such as Federally Qualified Health Clinics) have been reluctant to participate on their own in the ACO programs. The exclusionary effects of the risk levels that are imposed by the ACO programs is illustrated by the following simple example.

2. Example of the Intolerable Level of Risk Posed by Pioneer ACOs on PCP Groups

Let us assume that the ABC Primary Care Group has 10 PCPs, each of whom practices adult primary care; and that, if the ABC Primary Care Group were organized as an ACO, it would have 5,000 aligned beneficiaries with an average target budget of $10,000 per beneficiary and an overall target budget of $50 million. The payments made by Medicare to the PCPs included in the ACO for primary care services rendered to the 5,000 aligned beneficiaries of the ACO would account for a very small share (i.e., approximately 3%) of the target budget (partly because the aligned beneficiaries have no constraints on their self-referrals so not all of their PCP services would be provided by the PCPs in the ABC Primary Care Group). Therefore, let us further assume that, on average, the services provided by the PCPs in the ACO account for 3%, or $300 per aligned beneficiary, of the $10,000 average per beneficiary target budget. Our assumption that approximately 3% of the target budget would flow to the PCPs in the ACO is consistent with the actual payment experience of the Medicare program.

In the first year of the ACO Agreement, the ABC Primary Care Group would be expected to have a maximum liability of between 5% and 15% of its target budget, depending on the terms of its arrangement, and this risk level would increase to 15% in the third year. It is clear that a risk level of even 5% of the total budget (relative to the3% share of the total budget that would be paid to the PCPs) is far too high to be undertaken by any group of PCPs on a rational economic basis.

The fact that the risk imposed by the Pioneer (and SSP ACO) programs (initially or after the first three years) is too great to be borne by PCP groups can be demonstrated in the following way. First, let us assume that the maximum liability of the ABC Primary Care Group in the first year is 5%; and that this is the smallest liability that will apply over the three year ACO term. Further, let us assume that an unfavorable fluctuation in the morbidity of the ABC Primary Care Group's aligned beneficiaries produces a deficit and an associated liability of 3% in its target budget in the first Performance Year. In this situation, the 3% liability that the ABC Primary Care Group would owe to CMS would be equal to the total payments made by CMS to the PCPs of the ABC Primary Care Group for the services they provided to the ACO's aligned beneficiaries during the Performance Year. Thus, a relatively small fluctuation in morbidity, or in the cost control effectiveness of the ABC Primary Care Group, could wipe out its Medicare revenue and result in financially disastrous consequences for the PCPs.

It might be argued in the context of this example that the ABC Primary Care Group should or could have obtained a reinsurance arrangement from the private market as a risk protection mechanism. However, this argument is fallacious. As reflected in the SSP ACO regulations, CMS has found that groups of 5,000 aligned beneficiaries have substantial levels of expected variability in claims per beneficiary—i.e., they exceed 5% of the target budget. This statistic means that a reinsurer would charge a premium equal to 7% of the target budget in order to fully reinsure the PCMH for deficits above the minimum loss threshold (MLR) specified by CMS. The ABC Primary Care Group would, of course, need to pay for the premiums charged by the reinsurer from its claims payments. Thus, the PCPs in the ABC Primary Care Group would need to use all or nearly all of their Medicare payments for its aligned beneficiaries to fund their reinsurance premium.

The actuarial considerations related to the ACO risks borne by a more diversified physician group, such as a multispecialty physician group, suggest the same conclusion we have drawn for the PCP groups; namely, the risks faced by an IPA under an ACO arrangement would be excessive relative to the financial resources that are typically available to such groups. In the face of such risks, it is not surprising that PCPs and specialists generally turn to hospitals and health systems to obtain the financial backing that is needed to sustain the risks that are imposed by the Pioneer (and SSP ACO) programs. In many cases, the PCPs are recruited by the hospitals or health systems simply to ensure that the proposed ACO will capture a significant number of aligned beneficiaries. Unfortunately, as we have noted, the hospitals and health systems generally have financial interests that lead them to operate the ACO in ways that minimize savings.

3. Implications of the Risk Burdens Imposed by the Pioneer (and SSP ACO) Programs

The example presented above implies that the only organizations that are capable of prudently bearing the insurance risk of an ACO are hospitals or health systems that include hospitals. The inclusion of a hospital in a key role in an ACO is a potentially fatal design step for any ACO in regard to the goal of controlling health care expenditures. The greatest savings opportunities in health care are related to volume reductions. Hospitals (which still largely operate on fee-for-service reimbursement platforms) cannot reduce unnecessary admissions, readmissions, ER visits, surgical procedures and tests—or shift services to lower cost settings—without reducing their own revenues. This point is crucial because hospitals have fixed costs that are a substantial proportion of their average costs. The shared savings payments that are available under the Pioneer and SSP ACO programs are generally less than the fixed costs that remain when hospital volumes are reduced.

Hospitals typically lose money when volumes are cut. It is not realistic to expect hospital CEOs and CFOs to take steps, in the ACO context, o actively reduce volumes when the effects of these reductions are antithetical to their revenue and profitability objectives. The lack of significant savings under the Pioneer (and SSP ACO) programs, in a health care system that is often judged to include 20 to 30% waste, is evidence for one of our central theses—i.e., the inclusion of hospitals (and specialists) as core participants in a large proportion of ACOs has had an entirely predictable and profound dampening effect on the cost control vigor of these programs.

In short, the ACO risk arrangements limit the provider groups that can bear the ACO's required risk; these provider groups are, almost without exception, hospital-sponsored health systems; these health systems have business objectives that are directly counter to the ACO's goals; and, therefore, the Pioneer (and SSP) ACO programs—as currently structured—are highly unlikely to produce significant cost savings or to become vehicles for major health system reform consistent with the Three Part Aim.

D. The Effects of Years 3 and 4 of the Pioneer ACO Arrangement

The Pioneer ACOs are eligible for five years of participation under the ACO program. However, an ACO's options in Year 3 and the ACO's eligibility for continuation in the program depend on its performance in Years 1 and 2. Specifically, if an ACO does not, on average, realize target budget savings of 2.0% per year in Years 1 and 2, it is allowed to continue with its Year 2 risk arrangement in Year 3, but it is required to leave the Pioneer ACO program after Year 3. Given that only 13 Pioneer ACOs exceeded the Year 1 minimum savings rate (MSR)—which, in the two-sided arrangement, was 1% and, in the one-sided arrangement, varied between 2.0% and 2.7%—and 14 Pioneer ACOs had losses in Year 1, it seems clear that the annual target budget savings requirement may precipitate the termination of a substantial number of Pioneer ACOs at the end of Year 3.

For ACOs that, on average, realize target budget savings of 2.0% or more in Years 1 and 2, there are a variety of "population-based payment arrangements" that are offered by CMS to the ACOs that could apply in Years 3 and beyond. These arrangements depend on which of the risk arrangements the ACO selected at the beginning of the Pioneer ACO program. The only Pioneer arrangement with a one-sided risk structure (i.e., an arrangement in which the ACO bears no risk for deficits in its target budget in Year 1)—which appears to be the most frequently adopted risk arrangement—requires the ACO to accept full risk in Year 3 for all Part B claims, with a discount of 3% to 6% depending on the ACO's quality scores, and shared risk for Part A claims with a 70% maximum sharing rate. In the absence of a substantial savings level Year 2, it would be imprudent for an ACO to accept the third year terms of the Pioneer ACO Agreement.

The increased risk imposed on the ACO in Year 3 is exacerbated by the fourth year requirement that the ACO's target budget must be rebased in 2014 using the claims of the ACO's attributed beneficiaries in 2010, 2011, and 2012. As we will show in the detailed example that is presented in Appendix 1, the third year discount imposed on Part B claims, when combined with the fourth year rebasing requirement, makes it nearly impossible for an ACO with typical infrastructure and administrative costs to operate on a profitable basis unless it has relatively high quality scores.

The ACO program policies that require a minimum (2%) average savings rate over Years 1 and 2, a 3% to 6% quality-related discount on Part B target budget expenditures in Year 3, and a rebasing of the ACO's full target budget in Year 4 seem geared to eliminate all but the very best performers and to limit the 4th and 5th year participants to those ACO provider groups that are capable of bearing substantial insurance risks. These policies have the practical effect of making it financially imprudent for organizations that do not include hospitals/health systems to participate in the ACO program in Years 4 and 5.

E. The Problem of Unfunded ACO Infrastructure Expenditures

Every Pioneer (and SSP ACO) incurs expenses for administering the ACO program and for engaging in clinical management activities including case management, disease management, prescription drug review, care plan development and administration, management of evidence-based clinical protocols, etc. We will refer to these types of expenses, which are not reimbursable by Medicare, as "infrastructure" expenditures.

Many ACO arrangements that are established by private sector health plans—e.g., the "Alternative Quality Contract" (AQC) program operated by Massachusetts BCBS—provide Infrastructure payments by the sponsoring health plan to the participating provider groups. These payments make it more feasible for provider groups to establish and sustain ACO arrangements in the private sector.

The absence of Infrastructure payments under the Pioneer ACO has two undesirable effects. The first effect arises from the requirement under the Pioneer (and SSP) ACO programs

that infrastructure expenditures must be underwritten by the shared savings achieved by the ACO rather than through infrastructure payments by CMS. The savings generated by the ACOs are subjected to sharing percentages that are capped at levels that are substantially less than 100% (e.g., 50 – 70%) and they are adjusted downward unless the ACO achieves a perfect quality performance level. For example, in the third year of the risk arrangement, an ACO with a maximum savings sharing rate of 70% would probably see that 70% reduced by an unspecified amount depending on the ACO's third year quality scores. These fractional and uncertain savings sharing rates undermine the financial incentives that are supposed to motivate the ACO to adopt the clinical management activities that are crucial to the ACO's success in generating target budget surpluses.

For example, assume that an ACO projects that its Part A savings sharing rate in the third year of the risk arrangement will be 50%--i.e., the 70% maximum savings rate reduced by a quality score of .714 (50% = .714 x 70%)—and ACO's managers are considering the employment of a case manager at $100,000 per year to carry out discharge planning efforts that would be expected to reduce post-discharge expenditures. However, the costs of the discharge planner would not be reimbursable by Medicare, so the case manager would need to generate incremental savings of $200,000, under a 50% shared savings rate, to yield the $100,000 needed to cover his or her own costs. This example illustrates that ACOs are discouraged from undertaking any investments to manage costs unless they are very confident that these commitments will reliably generate savings that substantially exceed a two-to-one ratio.

The second undesirable effect of the lack of direct Infrastructure support payments from CMS derives from the policy of 4th year rebasing under the ACO program. Rebasing would strip the ACOs of the savings they use to fund their infrastructure costs. For example, suppose that an ACO has Infrastructure expenditures equal to 2.0% of its target budget and that in Years 1 and 2 of the ACO it has realized a target budget surplus of 4.0%. With a surplus sharing rate of 50%, this surplus would barely offset the ACO's infrastructure expenditures in Year 1 and might offset the ACO's Infrastructure expenditures in Year 2 (when the maximum surplus sharing rate would be 70%) depending on the ACO's quality score. Rebasing would eliminate the savings that would provide the funding for the infrastructure costs.

In effect, an ACO with these results would be completely responsible for funding the infrastructure expenditures that would be creating the Medicare surplus, and would be receiving no incentive payments in excess of its infrastructure costs in Year 1 and very limited (if any) such incentive payments in Year 2. Even with a perfect quality score, the ACO's incentive payments in Year 2 would be 2.8%, which is the 70% maximum savings share rate multiplied by the 4.0% surplus percentage. When these incentive payments are reduced by the assumed 2.0% of Infrastructure expenditures, the funds available to generate incentive payments for the ACO's providers would be 0.8% (i.e., 4.0% x .70 = 2.8% - 2.0% = 0.8%) of the target budget. By the end of the second year, the ACO would have generated accumulated savings equal to 8.0% of its target budget (4.0% in year 1 and 4.0% in year 2) and the ACO providers would have generated incentive payments of only 0.8% (0% in year 1 and .8% in year 2). This result would

occur even if we assume that the ACO would achieve the highest possible quality score in Year 2.

The rebasing requirement that would apply in Year 4 would make the ACO completely unenticing from a financial rewards perspective. The rebasing adjustment calculates the average claims per attributed beneficiary of the ACO for 2011, the last base year, and 2012 and 2013, which are the first two years of the ACO program. These claims would reflect the ACO's budget surplus of 4.0% in Years 1 and 2 and these savings would be expected to reduce the ACO's target budget in year 4 by 2 2/3% (i.e., 1/3 of the 4.0% reduction in Year 1 and another 1/3 of 4.0% reduction in Year 2 = 1/3(4.0%) + 1/3(4.0%) = 2.66%. Assuming that the ACO maintains infrastructure expenditures equal to 2.0% of its target budget, this 2 .66% target budget reduction, coupled with the 3rd year discount of 3% - 6% of Part B expenses, would make the 4th year recoupment of the ACO's Infrastructure expenditures a very daunting task. It would be remarkable if more than a few ACOs accept a continuation of the ACO program in Year 4 under the current arrangements.

F. Summary

We believe that the Pioneer and SSP ACO programs incorporate several basic design problems that will prevent them from achieving significant cost savings and from generating major reform effects. The key problems are the following:

- The Pioneer and SSP ACO programs impose levels of risk that vastly exceed those that can be rationally assumed by PCP groups or by most multi-specialty group practices. We strongly believe that PCP-driven care provides the best opportunity available to CMS to reduce costs and improve quality in the Medicare program. Unfortunately, the risk levels embedded in the ACO programs essentially require ACOs to be built on platforms that typically include hospitals/health systems. Hospitals have relatively high fixed costs and they view volume reductions, which are the primary source of cost control, as contrary to their financial interests. Therefore, ACOs that include hospitals are very unlikely to take the actions that are needed to save significant amounts of cost.

- The "net" savings sharing rates (i.e., the actual savings adjusted by the quality-adjustments) are too low to encourage ACOs to take the steps, such as investments in infrastructure, that are needed to substantially reduce costs.

- The required assumption of full risk for Part B expenditures in Year 4, at a quality-related discount of 3-6%, is an additional impediment to the continued participation of successful ACOs.

- The lack of direct infrastructure funding discourages ACOs from making investments in management activities that could substantially reduce overall costs.

- Finally, the rebasing requirement that is imposed after Year 3 eliminates the savings previously generated by the ACO and strips the ACO of its ability to support its infrastructure investments.

In combination, these features are lethal to the ability of the ACO programs to generate substantial savings or to promote the achievement of the Triple Aim. If CMS is interested in reviewing some possible solutions to these problems, we would be pleased to offer some recommendations.

Appendix One offers a detailed example of the design problems that are inherent in the Pioneer (and SSP ACO) programs and destroy their ability to generate savings and achieve major health system changes.

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Appendix A
Example of a Pioneer ACO
Benchmarks, Expenditures, Infrastructure and Incentive Payments
Over a Five Year Term

A. Assumptions and Preliminary Calculations

In this Appendix A, we consider a Pioneer ACO that adopts the Pioneer "Alternative 1" risk arrangement which includes 1-sided risk in Performance Year 1 (PY 1); a 50% maximum sharing rate, a 10% maximum sharing and related risk level in Year 2; and a dual risk arrangement in PYs 3-5 including full risk on a discounted Part B target budget, a continuation of the 70% sharing rate for the Part A target budget, and a PY 4 rebasing adjustment using claims data for 2011, 2012, and 2013. We shall refer to this Alternative 1 risk sharing scheme as the Risk Arrangement.

To simplify the computation of the ACO's Benchmarks, expenditures, target budget balance, and Incentive Payments in each Performance Year, we assume the following:

- The ACO's weighted average per beneficiary per year (PBPY) expenditures used to derive the Benchmarks is $10,000 and the annual trend applied to this baseline amount is $200.00 per year

- This means that the ACO's Benchmark in 2012 is $10,200 (the 2011 baseline PBPY amount, $10,000, increased by the 2012 trend of $200: $10,200 = $10,000 + $200); $10,400 in 2013; and $10,600 in 2014 prior to the discount applied to Part B services.

- In addition, we assume that the ACO's PBPY expenditures in each Performance Year are $10,000. This means that the ACO will have a surplus of $200 PBPY in 2012 (i.e., the $10,200 Benchmark less the $10,000 PBPY expenditures: $200 = $10,200 - $10,000) and a surplus of $400 PBPY in 2013.

In order to carry out the calculation of the 2014 Benchmark, we will assume that the ACO's target budget is 40% Part B and 60% Part A services and the ACO's quality performance in 2014 is at the 50^{th} percentile. This percentile ranking results in a 4.5% reduction in the Part B component of the ACO's 2014 Benchmark. The derivation of the 2014 Benchmark of $10,609.20 is provided on Schedule 4.

Schedule 1
ACO Benchmarks,
Expenditures and Incentive Payments

Performance Year	PBPY Benchmark	PBPY Expenditures	Surplus PBPY	Effective SP	Incentive Payment PB)
#1	$10,200	$10,000	$200	50.0%	$100.00
#2	$10,400	$10,000	$400	52.5%	$210.00
#3 Part A	$6,360.00	$6,000	$360	35.0%	$126.00
#3 Part B	$4,049.20	$4,000	$49.20	100%	$49.20
#3 Total	$10,409.20				$175.20
#4 Part A	$6,360.00	$6,000	$360	35.0%	$126.00
#4 Part B	$4,049.20	$4,000	$49.20	100.0%	$49.20
#4 Total	$10,409.20				$175.20
#5 Part A	$6,480.00	$6,000	$480	35%	$168.00
#5 Part B	$4,129.20	$4,000	$29.20	100.0%	$129.20
#5 Total	$10,609.20				$297.20

In 2015, the ACOs "rebased" Benchmark is $10,609.20, which is the same amount as the 2014 Benchmark. The derivation of the 2015 Benchmark is presented in Schedule 5.

The 2016 Benchmark is $10,409.20, which is the 2015 Benchmark of $10,409.20 increased by the annual trend of $200.00 (i.e., $10,609.20 = $10,409.20 + $200).

The ACO's quality percentile rank is assumed to be 100% in 2012, 75% in 2013, and 50% in 2014-2016. In each Performance Year, these quality percentile ranks will be multiplied by the maximum savings sharing percentage (SSP) to derive the effective sharing percentage (ESP) for the particular year. For example, in 2013, the ESP would be 52.5%, which is the product of the 70% SSP in 2013 and the 75% quality percentile ranking:

52.5% = .75 x 70%

The ESPs in 2014 - 2016 would each be 35%, which is the product of the 70% SSP and the 50% quality percentile rankings in each year:

35.0% = .50 x 70%

Finally, we assume that the ACO's infrastructure expenditures are $200 PBPY or 2.0% of the ACO's actual expenditures ($10,000) PBPY.

B. Benchmarks, Expenditures, and Incentive Payments

The ACO's Benchmarks, expenditures, and Incentive Payments in each of the five years of the Demonstration are set forth on Schedule 1. We will discuss the derivation of the Incentive Payments for Performance Years 1 and 3 to illustrate the calculations.

- Performance Year 1: In PY 1, the Benchmark is $10,200 PBPY, which is the baseline PBPY amount ($10,000) increased by the annual allowance ($200) for the first Performance Year, which is 2012. The expenditures in each PY are assumed to be $10,000 PBPY so the result is a surplus of $200 PBPY.

  In the one-sided PY 1 risk arrangement, the maximum SSP is 50% and the ACO's assumed quality percentile ranking is 100%. Therefore, the ESP in the first Performance Year is 50% (100% x 50%) and the Incentive Payment is $100 per beneficiary (PB), which is the product of the surplus PBPY ($200) and ESP (50%).

  $100 = 50% x $200

- Performance Year #3: Schedule 4 presented the Part A and discounted Part B target budgets of the ACO for Performance Year 3 on a PBPY basis as Part A = $6,360.00 and Part B = $4,049.20. The ACO's expenditures of $10,000 PBPY are comprised of $4,000 of Part B and $6,000 of Part A expenditures. The Part A target budget has a surplus PBPY of $360 (i.e., $6,360 - $6,000 = $360) and a maximum SSP of 70%. However, the ACO's quality percentile ranking in PYs 3-5 is 50%. Therefore, the ESP in Performance Year 3 is 35%, which is the product of the 70% SSP and the 50% quality percentile ranking:

  35% = 70% x 50%

Therefore, the Incentive Payment associated with the Part A target budget is $126.00 Per Beneficiary, which is the product of the $360.00 PBPY surplus and the 35% ESP.

The surplus in the Part B component of the Target Budget is $49.20 PBPY. Since the ACO's is fully at risk for its Part B expenditures, the Part B Incentive Payment is $49.20 Per Beneficiary, which is the full amount of the Part B target budget surplus.

As shown in Schedule 2, the impact of the ACO's infrastructure costs reduces the value of the Incentive Payments and diminishes the profitability of the ACO over the term of the program.

Schedule 2
ACO Incentive Payments vs. Infrastructure Costs and Derived P&L

Performance Year	PBPY Incentive Payments	PBPY Infrastructure	P&L
#1	$100.00	$200.00	($100.00)
#2	$210.00	$200.00	$10.00
#3	$175.20	$200.00	($24.80)
#4	$175.20	$200.00	($24.80)
#5	$297.20	$200.00	$97.20
Total	$957.60	$1,000.00	($42.40)
x 40,000 Attributed Members	**$38,304,000**	**$40,000,000**	**($1,696,000)**

C. Incentive Payments, Infrastructure Costs, and the Derived P&L by Performance Year

In this section, we add to our earlier assumptions by assuming that the ACO has 40,000 aligned beneficiaries in each year of the Demonstration.

Schedule 2 lists the ACO's annual Incentive Payments PBPY (which were derived in Schedule 1) and reduces these Incentive Payments in each year by the $200 PBPY infrastructure expenditures. Despite the ACO's continually favorable and improving Benchmark performance, the ACO loses money on a Per Beneficiary basis in PY 1 ($100), PY 3 ($24.80) and PY 4 ($24.80). These results illustrate the ratcheting effect of the Part B target budget discount in year 3 and rebasing in year 4 on the ACO Benchmark.

In the aggregate, the ACO receives $38,304,000 in Incentive Payments over the term of the program: this amount is derived by multiplying the total Per Beneficiary Incentive Payments over the five years of the Demonstration (i.e., $957.60) by the ACOs 40,000 aligned beneficiaries:

$38,304,000 = 40,000 x $957.60

However, these Incentive Payments are more than offset by the ACO's total infrastructure expenses payments of $40,000,000 during the term of the program. Overall, the ACO incurs a loss of $1,696,000 over the term of the Demonstration because the ACO's Incentive Payments of $38,304,000 are not sufficient to offset its infrastructure costs of $40,000,000.

In the next section, we will demonstrate the imbalance in the ACO arrangement by showing that the ACO lost money over the term of the ACO program at the same time that its

favorable and consistently improving Benchmark performance reduced the Medicare trust fund expenditures by more than $80,000,000.

D. Medicare Trust Fund Payment Increase versus the US Average

Schedule 3 compares the projected growth in the Medicare trust fund expenditures in each year of the ACO program with the actual trust fund expenditures for the ACO's aligned beneficiaries, including both their Part A and Part B claims plus the Incentive Payments made to the ACO for its Benchmark Performance.

The projected trust fund expenditures are derived from the $10,000 PBPY baseline claims in 2011 by increasing this amount by the $200 annual trend in each year. The Part A and Part B claims for the ACO's aligned beneficiaries are, by assumption, $10,000 PBPY as recorded in Column 2 of Schedule 3. The Incentive Payments PBPY are taken from Schedule 1.

In each year of the ACO program, the trust fund savings increase: they go up from $100 Per Beneficiary PY 1 to $703.80 in PY 5. With 40,000 aligned beneficiaries, the ACO produces aggregated trust fund savings of $81,696,000, which is the product of the total trust fund savings Per Beneficiary of $2,042.40 and the 40,000 aligned beneficiaries:

$$\$81,696,000 = 40,000 \times \$2,042.40$$

Schedule 3
ACO Projected Expenditures at US Trend versus
Actual Expenditures plus Incentive Payments

PYs	**PBPY with Projected US Trend**	**Actual Part A & Part B Expenses**	**Incentive Payments PBPY**	**CMS Payments (= c.2 + c.3)**	**Trust Fund Savings (= c.1 – c.4)**
	c.1	c.2	c.3	c.4	c.5
PY 1	$10,200	$10,000	$100.00	$10,100.00	$100.00
PY 2	$10,400	$10,000	$210.00	$10,210.00	$190.00
PY 3	$10,600	$10,000	$175.20	$10,175.20	$424.80
PY 4	$10,800	$10,000	$175.20	$10,175.20	$624.80
PY 5	$11,000	$10,000	$297.20	$10,297.20	$703.80
Total	**$53,000**	**$50,000**	**$957.60**	**$50,957.60**	**$2,042.40**
x 40,000 Attributed Members	**$2,120,000,000**	**$2,000,000,000**	**$38,304,000**	**$2,038,304,000**	**$81,696.00**

As shown in Schedule 3, by the fifth year of the Demonstration, the ACO is generating trust fund savings of $703.80 Per Beneficiary, which is a savings of 6.4% of the projected expenditures of $11,000 PBPY for the ACO's 40,000 aligned beneficiaries. Yet, despite this favorable Benchmark performance, the ACO's Incentive Payments are not sufficient to offset it

$200 PBPY infrastructure expenditures. These results illustrate the imbalance in the risk and incentive arrangements of the Pioneer ACO program as it currently stands.

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Supplementary Schedules

Schedule 4
Derivation of the 2014 Benchmark

Trended 2014 Base Year Claims	**$10,600.00**
Part B (40%)	$4,240.00
Part B Discount (4.5%)	
Part B Discounted (1- .045) x $4,240	$4,049.20
Part A (60%)	$6,360.00
Total 2014 Benchmark	**$10,409.20**

Schedule 5
Derivation of the 2015 Benchmark

Baseline Expenditures (Actual) Trended to 2013:	
2011	$10,400
2012	$10,200
2013	$10,000

2013 Benchmark Baseline (Average 2011-2013)
(1/3 x $10,400 + 1/3 x $10,200) + 1/3 x $10,000 = $10,200

2014 Trend (+ $200) = $10,400

2015 Trend (+ $200): Trended 2015 Base Year Claim = $10,600

Part B (40%) = $4,240
Part B Discount (4.5%):
Part B Discounted = $4,049.20
Part A (60%) = $6,360.00

Total 2015 Benchmark = $10,409.20

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March 1, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington D.C. 20201

Submitted electronically via CMS Innovation Center's website

Re: Center for Medicare and Medicaid Innovation Request for Information: Evolution of ACO Initiatives at CMS.

Dear Administrator Tavenner:

The Council for Affordable Health Coverage (CAHC) is pleased to comment on the Centers for Medicare and Medicaid Services' (CMS) Request for Information regarding the Evolution of ACO Initiatives at CMS.

CAHC is a broad-based alliance with a singular focus: bringing down the cost of health care for all Americans. Our membership reflects a broad range of interests—organizations representing small and large employers, manufacturers, insurers, brokers and agents, retailers, physician organizations and consumers. Our membership list is available on our web site at www.cahc.net. These comments reflect those of the Council and may not reflect the positions of our individual members.

CAHC supports testing innovative payment and delivery systems. In particular we think there is a great deal of value in engaging providers to improve quality through improvements in the coordination of patient care. The purpose of these models should be to determine the strongest arrangements for improvements in delivery of care in a more affordable manner.

Accountable care organizations (ACOs) in Medicare are a relatively new model. We believe further data and experience is needed prior to expanding the model or drawing any conclusions that can applicable to the Medicare population generally. At this point we believe the emphasis should be on stabilizing existing ACOs and collection of robust data that will eventually led to a more valuable model.

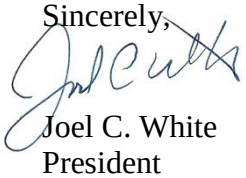
We caution that it may be premature to move to full risk bearing ACOs. Instead, we encourage interim steps to full risk bearing. As we move towards that goal, it is important to consider the impact of any changes to the ACO programs on beneficiaries. Medicare beneficiaries do not actively choose to participate in an ACO and they may be

funaware that an ACO is delivering their care. At a minimum, beneficiaries should be informed that they are participating in an ACO prior to the entity bearing full risk. Ideally, beneficiaries should be engaged financially in their care to help solidify a virtuous relationship between the provider ACO and the patient. We believe providing rebates or discounts on premiums or reduced cost sharing will help in this regard while also addressing leakage or patients who receive care outside the ACO.

Lastly, while CAHC appreciates the value of a coordinated care model, we continue to harbor concerns related to market concentration and consolidation amongst health care providers. High concentration by a few entities will tend to inflate the cost of care in an area. The impact of consolidation may not be evident in Medicare but there may be spill over effects into the private market. For example, highly concentrated markets may stifle price negotiations between private insurers and providers, which will increase costs for commercial payers, and ultimately, consumers who pay premiums. We ask CMS to keep this problem in mind as it considers policy changes to make the ACO programs more attractive to providers and beneficiaries.

Our specific comments to the questions posed by CMS are included in the attached document. We look forward to working with you to improve care coordination and lower costs in the Medicare program.

Sincerely,



Joel C. White
President

Section 1: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

Yes, we believe and have held discussions with multiple organizations who would be interested in participating in the Pioneer ACO program, but they cite the need for greater flexibility in program requirements. The small number of Pioneer ACOs relative to the many MSSP participants reflects not only stringency in program rules, but also a market in transition as Pioneers seek to put in place infrastructure, provider relationships and patient engagement strategies. We believe increasing flexibility related to two sided risk sharing arrangements and creating incentives to collaborate across payers will help foster relationships that generate cost sharing in local markets.

If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

CMS should not arbitrarily limit the number of organizations that want to be a Pioneer ACO. Such limitations are likely to depress the variation in delivery strategies and administration, which will in turn limit innovation. If an organization can meet the minimum requirements, we believe it should be allowed to participate.

Section II: Evolution of the ACO Model-A. Transition to Greater Insurance Risk

What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

To the extent that integration with Part D is pursued, we believe CMS should not undermine the Part D program, including competitive bids, availability of plans and variable benefit design. We believe allowing (or requiring) ACOs to accept Part D risk should be discussed openly with all stakeholders and that any changes that impact the program are readily understood and any negative impact is mitigated. We believe integrating the two different risk structures for ACOs and Part D is a complex undertaking that should be handled with the utmost care. Should CMS require or allow ACOs to assume Part D risk, ACOs should meet all the requirements of the Part D program.

What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of suing national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

Regional variations in health care spending are well documented, as is the fact that some of the variation cannot be attributed to input prices or differences in patient populations. Local references for expenditure growth will be more accurate, but may also capture part of regionalized and wasteful health expenditures. For these reasons, we believe the growth trend for benchmarking should be established as a blend of national and local growth trends.

What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Part A, B, D and/or Medicaid?

ACOs should be allowed to provide reduced cost sharing on benefits and rebates on premiums because it will more directly engage patients in their care. For example, an ACO could waive cost sharing for a physician visit to administer the influenza vaccine. Doing so promotes healthy outcomes for beneficiaries and also avoids the expenses that can be associated with the flu. Providing financial incentives to a beneficiary also helps avoid the problems associated with beneficiary assignment and patient leakage, two major problems highlighted by the recent Pioneer evaluation. It is important to permit as much flexibility as is possible.

Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO a full insurance risk rather than sole reliance on claim-based attribution?

As outlined above, we believe voluntary alignment would work well if beneficiaries received financial incentives, such as discounted premiums or lower cost sharing. We note that these are common tactics used by Medicare Part C and D plans and encompass key strategies in competing for covered lives in those programs. Under the current attribution model, beneficiaries may not even know or be concerned that they receive care under an ACO arrangement. With financial incentives, we believe beneficiaries will take a more active role in engaging in their health and with their ACO professionals.

Section II: Evolution of the ACO Model- C. Integrating Accountability for Medicaid Care Outcomes

What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare0Medicaid beneficiaries over 65 years old or under 65? Alternately, should the ACO be accountable for outcomes of all Medicaid

beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

Beneficiaries being cared for outside the ACO arrangement do not reflect on the proficiency of an ACO and should not be included.

What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

State resources, capability, and interests will vary. States should not impede the coordination of care for dually eligible individuals. If states are so inclined, they may consider mirroring financial arrangements for dual eligible individuals enrolled in Medicaid managed care organizations.

What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

If CMS takes this approach, CMS should take the lead on designing the financial arrangements best suited to recognize the proportion of shared savings attributable to Medicare or Medicaid. Medicare ACOs should be governed by Medicare program rules, and the providers who contract with CMS under these arrangements should have confidence in dealing with a single, responsible entity.

From: Newsom, Mark [mailto:Mark.Newsom@CVSCaremark.com]
Sent: Friday, February 28, 2014 5:55 PM
To: CMS PioneerACO
Subject: Request for Information

Please note that I attempted to submit using the online form. It appeared that some comments were cut off. Our full comments are provided below. Thank you for your consideration.

Would additional health care organizations be interested in applying to the Pioneer ACO Model?
CVS Caremark Response: Yes

Why or why not?
CVS Caremark Response: This is still a new program. Many national and regional health insurers in the commercial market have developed ACOs that are not yet part of the Medicare program. The management consulting firm Oliver Wyman estimates that 8-14 million patients are in non-Medicare ACOs. It makes sense to maintain the Pioneer ACO Model as an option for these and other organizations. We, therefore, recommend that CMS discern whether there have been any barriers preventing these entities from participating and, to the extent necessary, broaden the criteria to allow flexibility.

In settings with low adoption of ACOs, PDPs could enter into shared savings relationships directly with CMS to create a financial incentive to deliver adherence-improving and value-promoting interventions to beneficiaries.

If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?
CVS Caremark Response: ACOs are still in their infancy. Policymakers need to be flexible in order to make ACOs a firmly established model of care throughout the United States. We can see no policy rationale for limiting the number of selected organizations if they are meeting the CMS qualifying criteria.

Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?
CVS Caremark Response: ACO organizations generally do not have the infrastructure that Medicare Advantage Organizations have, and the ACO may have difficulty in many states obtaining licensure as an insurer, particularly with regard to solvency standards. For these reasons it would not be advisable for ACOs to attempt to become a Medicare Advantage Organization. The infrastructure issues are even more problematic for pharmacy benefits. This is why provider organizations that are currently Medicare Advantage Organizations generally contract with a pharmacy benefit manager (PBM) to handle the Part D side of the benefit.

We believe it would be beneficial for additional options to be created to provide opportunities for an ACO to collaborate with other entities that have the existing infrastructure to add value, such as pharmacy benefit managers (PBMs), chain pharmacies, and retail clinics. For example, to manage the Medicare prescription drug benefit, we propose that CMS fully support symmetrical (upside and downside) risk sharing on prescription drug expenses between ACO organizations and Medicare Part D stand-alone Prescription Drug Plans (PDPs) and symmetrical risk sharing between ACOs and PDP of Total Medical (A&B) Expense savings. Such models with Part D sponsors would support collaborations and impact of evaluating all components of care in terms of cost and quality. Risks are minimal if standard beneficiary

protections currently implemented in the Medicare Advantage and Part D programs are utilized in this context.

Are there services that should be carved out of ACO capitation? Why?
CVS Caremark Response: CMS must balance incentives to provide integrated care with infrastructure issues. With respect to Part D coverage drugs, it is clear that the typical ACO lacks the infrastructure to manage the drug benefit. It is also clear that under the current model ACOs may have an incentive to switch patients to Part D drugs and away from appropriate Part A or Part B treatments or procedures. A shared risk model between the ACO and a Part D sponsor would mitigate the risk of ACO cost shifting to Part D. It is not clear how CMS envisions a carve out model, so we would need to know more about that before commenting.

What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?
CVS Caremark Response: We support symmetrical (upside and downside) risk sharing on prescription drug expenses and/or Total Medical Costs between ACOs and Medicare Part D sponsors. From the CMS and Part D sponsor perspective a regulatory framework already exists. In Medicare Part D, gains or losses that the Part D sponsor may receive as a result of risk sharing arrangements are reported to CMS in the annual direct and indirect remuneration (DIR) report and CMS adjusts Part D sponsor payments accordingly.

Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?
CVS Caremark Response: In the 2013 Call Letter to Medicare Advantage Organizations and Part D Plan Sponsors, CMS articulated "an interest in sponsors of stand-alone prescription drug plans (PDPs) playing a greater role in managing the care of Medicare FFS beneficiaries and having greater accountability for overall health outcomes" and CMS encouraged ACOs and Part D plans "to form appropriate business arrangements that support improved pharmacy care coordination." We would like to thank CMS for their ongoing support of collaboration between ACO and Part D Sponsors.

Data sharing between CMS, ACOs, and non-ACO entities is the most significant barrier. For example, determining the appropriate level of medication therapy management (MTM) services targeted to the appropriate beneficiary provides the opportunity to (1) optimize therapeutic outcomes through improved medication use and (2) reduce the risk of adverse events. It is impossible to accurately assess clinical complexity issues that can best be ameliorated with appropriate MTM interventions without the full spectrum of pharmacy and medical claims, diagnostic, and testing records available for the beneficiary across programs and providers. Comprehensive data sharing is also necessary to determine patient non-adherence and to develop reporting on cost efficient care options. The lack of access to these data is a significant barrier to establishing expected cost benchmarks based on patient populations and disease prevalence, and risk sharing arrangements around these benchmarks. We also believe the lack of data sharing is a missed opportunity to conduct proper utilization management and increased oversight to prevent prescription drug abuse.

CMS also requires PDPs to include the cost of clinical programs aimed at improving adherence to essential medications in the administrative cost in their minimum Medical Loss Ratio (MLR) metric. By doing so, CMS is creating a disincentive to apply potentially cost-saving and quality-improving interventions. These costs should not count towards administrative expenses in the MLR.

What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?
CVS Caremark Response: We urge CMS to encourage ACOs and Part D sponsor to share data and to provide comprehensive guidance on the permissibility of data sharing between these entities. We also urge CMS to consider granting ACOs and Part D sponsors, with limited access to the CMS Integrated Data Repository (IDR) for the purposes of having more comprehensive beneficiary level Medicare data necessary for care collaboration. We also urge that CMS allow PDPs flexibility in MLR calculations for costs related to ACO activities.

If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?
CVS Caremark Response: We reiterate that it would be inappropriate for ACOs to assume full and sole Part D responsibility. ACOs should partner with existing Part D sponsors. That is the best model to achieve the potentially conflicting goals of cost control, care coordination, and maintaining appropriate beneficiary protections.

Mark Newsom | CVS Caremark | Director, Public Policy | Phone: 202.772.3530 | Mobile: 202.603.4742 | 1300 I St., NW, Washington DC 20005 | mark.newsom@cvscaremark.com

RFI: Evolution of ACO Initiative at CMS

The Centers for Medicare & Medicaid Services (CMS) are seeking input on the following areas related to the evolution of Accountable Care Organization (ACO) initiatives.
1. A second round of applications for the current Pioneer ACO Model
2. New ACO models that encourage greater care integration and financial accountability

Instructions: The following survey lists the questions found in the Evolution of ACO Initiative RFI which can be accessed through the CMS Innovation Center website at http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/ Please note that you are not required to answer all of the questions in the survey prior to submission, only those that you prefer to answer. Please also note that the text boxes below do not have a character limit.

Submission Date for Comments: To be assured consideration, comments must be received by March 1, 2014.

- Organization Name : Dartmouth-Hitchcock Health and the Northern New England Accountable Care Collaborative
- Point of Contact Name Lynn First Guillette Last
- Email : Lynn.M.Guillette@Hitchcock.org
- Phone Number 603-653-1255
- Please select the option that best describes you.

  ○ Part of a Medicare ACO ○ Part of a Commercial ACO ● Part of both a Medicare ACO and a Commercial ACO ○ Not part of a Medicare ACO or a Commercial ACO

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

   Organizations not currently Pioneers but that have been successful as SSP ACOs likely would have interest in becoming a Pioneer because some of the model differences would likely be seen as more favorable. In particular, the 1% fixed MSR, opportunity for greater than 50% risk sharing, and prospectively determined attributed population might be preferred. The ability to have Nurse Practitioners considered as PCPs also would be attractive to some organizations. The biggest deterrent to new Pioneer applications would be the magnitude of downside risk relative to the model's economic complexity and developmental instability, current inability to provide Pioneers with "sub-ACO Benchmark targets" for distinct geographic participants in the ACO, and the current lack of closer to real time provision of performance measures that could afford an ACO adequate notice to take corrective action within a performance year.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

   The primary reason to limit Pioneer acceptance is to preserve the high level of support that CMMI has been able to afford the Pioneers to date. If accepting all qualifying ACOs would lead to a reduced service level then limits should be set.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

   The biggest refinement that would provide greater comfort for ACOs to seek Pioneer status would be to provide for greater beneficiary "skin in the game" to manage total cost of care. Allowing unfettered access to services anywhere regardless of ACO endorsement of the service need or appropriateness is concerning to providers taking two-way risk. Other refinements that would help attract ACOs include:

   -providing full access to claims data including Substance Abuse and Behavioral Health data

   -eliminating the data sharing opt out provision; or if unable to eliminate this provision, then exclude any beneficiary opting out of data sharing from the ACO risk population

   -allowing members to "attest into" an ACO

-improving the Risk Adjustment perhaps using the Medicare Advantage approach but certainly eliminating the matched cohort approach that is not understandable and may not sufficiently risk adjust over time.

Lastly, some Pioneer ACOs have significantly expanded their ACO participant rosters beyond the core group of providers included in the initial Pioneer model application in 2011. Many did this to increase the geographic reach of the Pioneer model in their respective market places. However, the current Pioneer ACO baseline benchmark methodology was designed based on the premise that the initial core provider roster identified at the beginning of the three-year agreement period remained static except for routine hires and terminations, but did not contemplate additions of entire health systems or large physician group practices to the ACO over that three-year time period. The model will have to be refined to accommodate these type of provider expansions in order to achieve the goal of achieving the Triple Aim more and piloting these type of advanced payment models more broadly.

Population-Based Payments:

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

YES.

Given the variability of in most Pioneers and MSSPs participant construction, PBP should be flexible enough so that they reflect the relative proportion of overall *participant* payments for attributed beneficiaries accounted for by Part A versus Part B payments. So for example, a more 'facility' based ACO could request that a higher proportion of Part A based payment be considered for their PBP than a multi-specialty physician based ACO might. We recommend that there be enough flexibility in the model so that these proportions can be modified by individual ACOs to reflect their willingness and ability to take more risk. For example, a multi-specialty physician based ACO that has been very successful in managing hospital-based utilization could ask for a high % PBP.

However, our overall recommendation is that an alternative model rather than alterations in the current PBP model is more appropriate (see responses to **transition to greater insurance risk** questions).

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

YES.

As a general principle, ACOs should be encouraged to extend their participants to include providers of any services/supplies that are deemed important for delivering on the triple aim. These would include DME suppliers, but could also include retail pharmacies, hospice providers, etc. Current ACOs lack scope and resources for managing chronic illness and

helping patients with chronic illness navigate effectively and efficiently through the healthcare system. Incorporating the best aspects of the current ACO models while selectively reaching into the acute care sector and out to community providers will result in true patient-centered, coordinated care. The goal is to move towards the development of a *medical neighborhood* model. This would require ACOs to incorporate additional providers into the patient-centered team, including medical and surgical specialists (specialty providers, many of whom are not currently participants), clinical pharmacists, palliative care providers, behavioral health providers, DME providers, and community organizations. These new models recognize that longitudinal care requires shared accountability across a variety of settings. These relationships need to be supported by payment models that support and incentivize these providers. Therefore, risk based contracts should allow flexibility for a wide variety of relationships among suppliers. In addition to extending PBP payment models to these providers, CMMI should allow ACOs to enter into gain sharing models with these participants, as is allowed in the BPCI).

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

YES.

The shared savings payment models under which Pioneer currently operates has required a "leap of faith," promising that investments and ongoing operational costs designed to address over- and under-use *now* will result in improvements in the health of the population and a return on investment in the *future* when the final reconciliation process has been completed. This challenge is amplified by fact that these programs are for attributed Medicare beneficiaries only (see below). These circumstances have resulted in a "tragedy of the commons" wherein systems operate under the volume-based reimbursement model and address obvious and easier clinical opportunities that require minimal investment, but do not fully engage in those interventions likely to significantly reduce utilization and cash flow and/or require a full transformation in how clinical care is delivered.

'Failure' to generate a specified level of savings in previous years is confounded by the transition payment model that shared savings reflect. Therefore, we recommend that CMMI create an alternative model for those ready to assume more risk. However, it is not given that this should be based solely on financial reserves, in fact we recommend other risk-mitigation strategies that would include provision of reinsurance (purchased by the ACOs), withholds, and others (see below).

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

NO.

Transition to greater insurance risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

YES (with modifications from Medicare Advantage).

In order to move the ACO effort forward, and to answer the question 'what happens after shared savings ends', will require creative effort on the part of CMS and providers. Many providers are ready and willing to participate in risk based efforts with CMS for both Medicare and Medicaid beneficiaries. However, we do not support the extension of the Medicare Advantage (MA) program as the preferred model. Rather, we would like CMS to consider a hybrid model where CMS and interested ACOs develop a partnership that leverages their unique capabilities to develop a prospective, risk-based, capitated payments for attributed Medicare FFS, Dual, CHIP, and Medicaid populations (see responses below to recommended modifications to the current attribution models).

This would entail that CMS continues to perform many of the typical 'member services' that an MA plan would do as CMS currently does: enrollment, claims processing, network development, eligibility assessment, etc. The ACO would be responsible for creating the local extended 'network' required under more progressive risk models. This would require them to extend the participants to other providers not currently considered as participants (e.g. DME, retails pharmacies, etc.); to create the gain sharing models *within* the ACO for the current and added participants, distribute gains/collect losses, etc. It also will require the ACO to add additional member services to increase 'loyalty', promote health, etc.

We propose that CMS maintains the infrastructure, roles, and processes needed to implement the prospective, risk-based, capitated payments for attributed Medicare FFS and Duals. The prospective payment would be based on historical payments to ACO participants, with a 'withhold' for historic out of ACO payments. Participants would submit bills as they would under FFS, however, CMS would use a $0.00 payments claim adjudication methodology for submitted claims for ACO participating providers. Prospective payments would address both the cash flow impact of successful care coordination services AND act as a change management lever to support and alter FFS 'behavior' that is a drawback of the current Pioneer and MSSP programs. Further, the prospective payments will be used by the systems to invest in infrastructure and personnel to implement new care models and new provider compensation models. Non-ACO participant providers will be paid by CMS under usual FFS Medicare.

We would recommend that CMS require the ACO participants to submit claims allowing CMS and the providers to assess and value the volume and types of care being delivered under these new models; allowing CMS to reduce the risk of the ACOs withholding valued services to beneficiaries, and both CMS and the ACOs to measure total services and monitor some of the quality metrics.

CMS should consider several strategies to mitigate the risk of the ACOs being unable to re-pay CMS should costs grow at a rate greater than the targeted growth. For example, CMS could require a pre-specified amount of the prospective payment be held in escrow by the

systems as reserves in case the system needs to repay CMS (if the global budget target is exceeded); CMS could require reinsurance be purchased (ideally, CMS could act as the reinsurer), etc.

Consistent with the hybrid approach, we would encourage CMS to develop an ACO beneficiary benefit design that can continue to allow for freedom of choice but would have some differential beneficiary cost sharing if that member opted to receive elements of care from a non-ACO Participant for a service that was included in the payment bundle or capitation responsibility of the ACO.

See further detail below.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

We believe that the ACOs should be at risk for Medicare and Medicare-Medicaid A, B, and D; we recommend that some services be carved out (see below).

3. Are there services that should be carved out of ACO capitation? Why?

YES.

The ACOs should be primarily at risk for medical services only. This encompasses the majority of services paid for by Medicare. However, to the extent that the Medicare-Medicaid beneficiaries (Duals) and Medicaid enrollees (see below) are included, services such as Long Term Support Services (LTSS), transportation, and other types of custodial or non-medical services should be carved out from the risk contracts.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

ACOs at full insurance risk will need the flexibility to make a variety of arrangements with non-ACO providers (as allowed in BPCI). As noted above, at a minimum ACOs will need the latitude (and regulatory relief) to enter into gain sharing relationships with entities such as home health and hospice agencies, DME providers, retail pharmacists, and community based mental health providers.

Further, ACOs should be allowed to include non-traditional providers in the care team, covering their reimbursement from the prospective population-based payments. For example, as the care team extends to include community based service providers, the ACO should be able to contract with them and use the risk based payments from CMS to reimburse them.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-

bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

In NH currently providers in risk contracting are not subject to state licensure requirements for risk bearing entities. However, the growth of ACOs and risk bearing contracts had led the state Department of Insurance to begin considering what, if any, requirements should be developed. As a federal program, we would prefer these requirements be largely established by the federal government and that Pioneers be provided with a waiver opportunity to avoid added cost of state compliance. In particular, if a State adopted a substantial bonding requirement for a risk bearing entity that would certainly be a big negative influencer for greater ACO Participation.

CMS needs to recognize that many ACOs function in relatively rural areas where few providers exist. Thus, some ongoing anti-trust waiver will be needed to permit these rural providers to collaborate effectively around ACO and Triple Aim goals.

ACOs will request that they receive waivers to several regulations and fraud and abuse laws if they are to enter into full (or partial) insurance risk models. These would likely include:

- 72-hour stays before referral to SNF
- Homebound criteria for home health services to be covered
- Requirement that ER patients be hospitalized before they can be transferred to a transitional care facility
- Requirement for an in-person physician visit within 30 days of in-home care
- Inability for nurse practitioners to authorize home care
- Anti-kickback Statue – CMS should support the extension of the 'safe harbor' regulations to allow gain sharing among providers who bear risk (even those who are not corporately part of the accountable system, as has already been addressed in the BPCI)
- Stark Law – Selective incentives for referrals to providers within the system should be allowed to foster integration
- Patient Choice Requirements – CMS should support the relaxation of the patient choice requirements to allow referrals to those entities that are part of the accountable system (for example home health)
- Quality Reporting- the Physician Quality Reporting System is focused on individual physicians and not system level care delivery. Meaningful Use standards force processes that may not help deliver and document the medical care needed. Hospital Quality Reporting continues to be focused on hospital care. The Annual changes in Reporting Requirements for each program (PRQS, MU, HVBP) does not provide the opportunity for systems to invest in processes that assure best outcome or in outcome measures that have defined, valid processes that assure best outcomes that are meaningful to beneficiaries. Ideally an ACO that keeps costs at historic levels but demonstrated a significant improvement in quality should be able to receive an economic reward within the payment model since the value of

care would have been improved even though the cost of care alone did not decrease.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

As noted above, we do not recommend that CMS follow the 'traditional' Medicare Advantage model as they consider insurance risk models. We recommend that Medicare maintain many of the functions that require infrastructure (enrollment, notification, claims processing, 'network management', etc.). However, we do recommend that ACOs contemplating risk-based models invest in information services infrastructure to increase the likelihood of success under these models. This infrastructure should focus on population segmentation, beneficiary outreach, care coordination, physician performance assessment, contract management, etc. ACOs will also need to develop, or contract for, expertise in such areas as actuarial services.

An additional area of investment ACOs will need is beneficiary 'engagement' strategies and operations. This will be particularly important in more competitive markets where beneficiaries are more likely to receive care from non-ACO providers. In these markets, creating beneficiary 'loyalty' that results in greater within ACO utilization will be a key success factor (see below for additional comments on this issue).

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

Ideally, CMS and its constituents would make an explicit decision about the total amount of health care services per capita it would purchase using a deliberative process. Recognizing that this is unlikely to occur in the foreseeable future, we recommend that CMS stay with a modified NATIONAL expenditure baseline. CMS should develop a method that allows those regions that are significantly below national averages in total expenditures to grow at a rate that is marginally above the national growth rate, conversely, those that are significantly above national averages in total expenditures to grow at a rate that is marginally lower the national growth rate.

We recommend strongly AGAINST a local reference expenditure growth trend. For both reasons of concern that a local growth rate target would lock in healthcare spending disparities AND for methodological reasons including regression to the mean advantaging high outliers and disadvantaging low outliers, instability in estimates, and most critically, the variance of performance within a region, we believe that a local growth rate target would be inappropriate.

9. What are the advantages or disadvantages of different strategies for risk-adjustment?

(Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

The current MA risk adjustment is fundamentally flawed. Specifically, the reliance on claims based diagnoses over adjusts for health status risk in high utilization/high spend providers and under adjusts for health status risk in low utilization/low cost providers. Evidence of this bias has been revealed in recent papers by the Dartmouth Institute faculty, assessment of the PGPD results and in the 'revenue optimization' venders who provide services to MA plans.

We strongly recommend that CMS uses an alternative risk adjustment process for ACO and other risk based contracts (including MA plans). Recent evidence suggests that a combination of demographic adjusters combined with self-reported health status information (e.g., smoking status, BMI, functional status) provides a much more defensible risk adjustment and avoids the bias inherent in all claims based methods. Further, such an approach also will provide the data needed to extend the patient experience and health outcomes measures that will become standard in all value based contracts.

10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

Encouraging and incentivizing beneficiaries to stay within ACO participant providers is a key risk mitigation strategy for beneficiaries from an outcomes perspective and for the ACO from a financial perspective. Given that more fundamental modifications to traditional Medicare benefits are unlikely, we recommend that CMS consider reductions of both co-pays and deductibles for Medicare beneficiaries who receive care from ACO participant providers. For those providers who have the capacity and capabilities, other enhancements to benefits, such as routine vision care, should also be allowed to encourage loyalty. Finally, as Medicare moves to prospective, risk-based, capitated payments other clinical interventions (e.g. group visits with health educators), integration with community health, etc. should be allowed and encouraged. Finally, the ACOs will need to be allowed to use these benefit enhancements in their beneficiary communications.

While waiving of copays and deductibles is not applicable, ACOs should be able to supplement benefits to Medicaid enrollees as well. For Medicaid this could include transportation (e.g. taxi vouchers), extending home health, etc. Allowing for home health coverage among ACO beneficiaries not meeting strict homebound criteria but who have a care plan promoting self care management with home health support should be considered.

PART D….not sure yet. We have little experience with this but our pilot program with CVS Silverscripts Plan D program has created a good partnership platform. Our understanding, however, is that CMS has not had a stable model/rules to risk share with CVS which then cascades down to our ACO arrangement. We would like the ability to direct market the

Plan D ACO partners to our ACO beneficiaries since partnering on med management and compliance is critical for total cost of care not just the Rx cost portion.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection? CMS might invoke some type of "3 R" protection for full risk ACOs similar to what has been affected for the new insurance exchanges. Having more robust risk adjustment also helps protect against adverse selection.

The ACOs recognize that CMS needs to be vigilant regarding freedom of choice.
However, while CMS is concerned with abuses, the ACOs will ask CMS to modify their beneficiary communication and notification rules. The current MSSP and Pioneer models for beneficiary communication are cumbersome, bureaucratic and the approved communications are poorly designed. Further, if CMS is interested in ACOs managing prospective, risk-based, capitated payments the ACOs need to have some latitude on referrals to aligned providers. ACOs will need to work with CMS to balance these interests.

CMS should monitor the ACOs for their 'churn rate'. Based on a reference population, CMS could set upper thresholds for churn that if crossed would obligate trigger investigation.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

YES. The benefits are primarily related to the ACOs' interest in loyalty, and the beneficiary's interest in high quality, value based providers. Further, to the extent that CMS allows, and the ACO offers, additional benefits, the beneficiary may be at lower risk for out of pocket expenses and have access to services that Medicare has not historically paid for.

The primary disadvantage is that this could potentially offer adverse selection: more healthy beneficiaries may be encouraged to voluntarily join. To avoid, or at least adjust for this possibility, CMS must choose a valid risk adjustment process.

Integrating accountability for Medicare Part D Expenditures

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and

outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

The primary barrier to better integration and risk sharing between ACOs and Part D carriers is that the market is highly disaggregated. Thus, if an ACO wanted to have these types of alignments, they would often need multiple relationships within a market. However, in some markets, ACOs will most likely wish to pursue participant relationships with one or more Part D providers and/or create a Part D plan of their own (with or without a partner).

CMS could greatly facilitate these relationships by requiring data sharing, encouraging appropriate gain sharing and marketing of specific plans (including through regulatory relief), and loosening the reserve requirements for those providers who want to create or sponsor their own Part D plan.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

Yes, ACOs would be interested in accepting this insurance risk as medication management, reconciliation, and appropriate drug substitution are all big contributors to helping manage medical cost as well as prescription cost. We encourage CMS to create a unified expenditure target for Part A, B, and D combined. Such a target will a) reduce complexity; b) allow expected increases in Part D costs to be offset by likely resulting reductions in Part A and B costs (particularly for targeted conditions such as mental health); and c) incentivize ACOs through total costs models to actually manage total costs.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

Maybe. CMS will need to improve Part D data capture (including those that arise through employer sponsored plans), and timeliness of the data transmission to ACOs. We are set up to receive this data now but CMS would need to ensure robust and timely submission. This could be accomplished by making this a requirement of Plan D providers. Our limited experience with one Plan D provider is that they have excellent data and willingness to support sharing if CMS rules can permit this.

Integrating accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

Qualified YES. ACOs are interested in increasing the total population 'under management' to include Medicaid populations. However, providers have had varied success in engaging and working with their state's Medicaid program. This variability is driven by local program designs, variation in reimbursement rates, and inabilities to honor contractual relationships on the part of the state (e.g., tax and match programs that become only tax programs).

We would look to CMS to support our engagement with the Medicaid program so that we can deliver high quality, effective, and efficient care for this disadvantaged population while at the same time not losing too much money. A major issue in this development is that some state Medicaid payments are so low that there is no opportunity to support any additional administrative costs to develop the many needed supports that a Medicaid population would have under a risk arrangement. Thus, for a Medicaid ACO to work effectively, there would have to be a minimum level of payment adequacy.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

We recommend that all Medicaid populations be included, but not all services (e.g. LTSS as noted above). We recommend that CMS use an attribution model. This will require minimum eligibility for attribution. Therefore, not all enrollees of all programs will be eligible.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

Not surprisingly, capabilities and interests vary greatly across States. If ACOs are to take risk, the States will need to be active participants in the design, implementation, and operation of these programs. CMS should ensure that states make the necessary economic and operational support needed to legitimately support ACOs taking Medicaid risk. This would include having an adequate emergency mental health system to ensure acute care hospital and other medical costs are not incurred because of lack of state access/resources to the true psychiatric need of the ACO beneficiary.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

Not surprisingly, capabilities will vary greatly across ACOs. We have invested in the technology and personnel to perform these data integration efforts. The Northern new England Accountable Care Collaborative (NNEACC), LLC is a shared services organization that currently supports 2 Pioneer and 2 MSSP entities. NNEACC integrates clinical data from laboratory, EHR, and HIE systems, claims from Medicare and commercial payers, and administrative data from a variety of sources. Once integrated, these data are augmented with predictive models and measures. This population health management information is presented to care coordinators, physicians and financial administrators through secure web-based workflow tools. CMMI could facilitate the development of NNEACC and other similar organizations through funding HIE and facilitating the scaling of common coding schemes.

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

While ideally this financial arrangement would be under one entity- presumably Medicare- given the tremendous variation in how states have implemented and operate their Medicaid programs, these will need to be separate. However, we do strongly encourage CMS and the States to coordinate their efforts with interested ACOs.

Other Approaches for Increasing Accountability

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

We believe that such a model will be important for rural areas. A drawback with the current Advance Payment ACO SSP model is that is does not permit hospital participation with the FQHCs yet in rural areas the community hospital is a significant provider of specialty care and outpatient services. Thus, a model that can allow for multiple community providers to participate is important to develop. We are exploring the development of a Community Care Organization in rural northern NH to achieve this. This model will be a hybrid of the ACO and historic PHO concepts and will include hospitals,

FQHCs, Community Behavioral Health providers, and Home Health providers. We are exploring using a rural health consortium organization to help achieve the necessary community integration. An important element of this model will be to create the appropriate environment for commercial payer populations to be included. Having these excluded will make it very difficult to achieve overall success but might require state and federal involvement to achieve.

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

Yes this would be of interest as a model. A key consideration of a model that would include primary care (potentially on a capitated basis) and risk sharing around other costs of care paid on an episodic basis would be the financial integration of bundled payment and distribution within the ACO having primary care responsibility. Permitting direct payments of the ACO to other providers involved in episodic care within the bundle might be important to allow.

Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

Not sure this is important. As ACO Delivery systems are formed, they will push other payers into a similar contract approach because providers do not practice different standards of care by payer, rather they strive to provide the best care to all patients regardless of insurance. The commitment needed to be successful as a Medicare ACO will compel these ACOs to insist on some type of comparable arrangement with commercial payers to help pay for the substantial infrastructure investment that must be made for an ACO and its participants to perform. Another impediment for commercial ACO development in more rural markets could be the inability to meet minimum attribution criteria. This would certainly be true in markets where there is an older population that is predominately covered by Medicare and in which the local providers have limited commercial populations to draw from.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

Ensuring at least a "common core" of measures can be utilized across all payers would be useful. Perhaps there is a way for CMS to use its direct licensure and state relationships with state department of insurance licensure to compel this adoption of common core. Establishing a "common core" of measures across multiple payors that encompass Medicare, Medicaid, and commercial payors will need to include measures for pediatrics and women and maternal health.

February 28, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-Evolution of ACO Initiative at CMS and Comments due by March 1, 2014

Dear Administrator Tavenner:

On behalf of DaVita HealthCare Partners, the 765,000 coordinated care patients and 168,000 end-stage renal disease patients we serve, and our 53,000 teammates dedicated to their care, we are pleased to provide input to the evolution of the ACO initiative at CMS.

As you know, HealthCare Partners has long been a strong advocate for coordinated care and believes it is a key element to the transformation of the US healthcare system. The Accountable Care Organization (ACO) is one subset of the coordinated care model.

We were among the earliest Commercial (e.g., Dartmouth – Brookings) and Medicare (Pioneer CA, Pioneer NV, and Pioneer FL) ACO provider group participants. We are participating in Anthem and CIGNA Commercial ACOs, and transitioned on January 1, 2014 to the Medicare Shared Savings Program in CA, NV, and FL.

We continue to evolve our clinical model to improve our patients' health outcomes, to increase patient satisfaction, and to bend the cost curve. Similarly, the Pioneer and Medicare Shared Saving Program must evolve if Medicare beneficiaries transitioning from fragmented fee-for-service will benefit from coordinated care and if US tax payer savings are to be realized.

Here are three recommended enhancements to the evolution of the ACO program we have shared with Dr. Gilfillan in the past and Dr. Pham:

1. Transforming toward a population health care model is a multi-year effort and ACOs are less likely to invest in specific ACO programs (e.g., GPRO) when there is a poor likelihood of achieving immediate savings.

2. Executional issues including the timeliness of data sharing with ACOs, inability to identify patients in acute and sub-acute environments, and inadequate risk adjustments (e.g., Duals) hampered our ability to further improve quality and reduce costs.

RFI: Evolution of ACO Initiative at CMS

The Centers for Medicare & Medicaid Services (CMS) are seeking input on the following areas related to the evolution of Accountable Care Organization (ACO) initiatives.

1. A second round of applications for the current Pioneer ACO Model
2. New ACO models that encourage greater care integration and financial accountability

Instructions: The following survey lists the questions found in the Evolution of ACO Initiative RFI which can be accessed through the CMS Innovation Center website at http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/ Please note that you are not required to answer all of the questions in the survey prior to submission, only those that you prefer to answer. Please also note that the text boxes below do not have a character limit.

Submission Date for Comments: To be assured consideration, comments must be received by March 1, 2014.

Organization Name: HealthCare Partners, LLC

HealthCare

Point of Contact Name Robert First Klein Last

Email: Rklein@healthcarepartners.com

Phone Number 310 - 630 - 4126

Please select the option that best describes you.

- ○ Part of a Medicare ACO
- ○ Part of a Commercial ACO
- ◉ Part of both a Medicare ACO and a Commercial ACO
- ○ Not part of a Medicare ACO or a Commercial ACO

2A. What are the advantages and/or disadvantages of either approach?

Allowing for more organization would foster additional creative strategies to evolve under the model. Limiting the participants would allow for more focused efforts toward the newer participants, addressing universally acknowledged issues and achieving better outcomes.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model? Yes, a capitation model with the waivers, flexibility, and structure employed under Medicare Advantage would increase the number of qualified applicants. Upside participation especially in the early years would also increase the number of applicants.

Yes, a cap

B. Population-Based Payments: CMS allows Pioneer ACOs to transition to population -based payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a 40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which

the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP?

(•) Yes

( ) No

1A. Why or why not? Not all Pioneers are health delivery systems. Inpatient relationships and cost containment strategies vary vastly differently from the professional aspects.

Not all Pior

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?

(•) Yes

( ) No

2A. Why or why not? Pioneers should be able to use appropriate cost containment measures, including with suppliers of DME equipment.

Pioneers sl

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves?

(•) Yes

( ) No

3A. Why or why not? Even in an advanced managed care environment, generating savings likely requires 1-2 years versus a single year time frame. It is important that ACOs invest in needed infrastructure and aligned incentives to employ strong population health programs.

Even in an

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

(•) Yes

( ) No

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries) Part D and Medicaid should not be part of the risk equation. An issue that needs to be addressed is the Medicare/Medicaid secondary payment. In the CA Duals pilot, the State should be responsible for costs not covered by Medicare like the 20% coinsurance.

Part D and

3. Are there services that should be carved out of ACO capitation? Why? ACOs should exclude transplant costs >$100,000 and the new biologic and oncologic injectables. These are infrequent items that incur substantive expense. These costs have an unpredictable impact on capitation and are therefore difficult to control/manage.

ACOs shou

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population? A preferred or tiered network maintains the opportunity for patients to have substantive choice. This would encourage patients to receive care provided by higher quality or more efficient providers. Reimbursement level no higher than 100% Medicare FFS.

A preferred

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk?

What regulatory and compliance elements in Medicare Advantage would NOT be appropriate for ACOs assuming full insurance risk?

The regulatory framework must allow for the Medicare Advantage waivers (e.g., payment for transportation, vision, hearing, etc.) that result in high quality and in lower costs. Members should be directly attributed to ACO organizations so we can engage them in their care. The preferred network referenced above. There are a variety of clinical enhancements (e.g. void the 3 day acute admit rule before SNF admissions).

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities?

What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

The challenges vary by State. The anti-kick back rules that prevent the use of a preferred network.

Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services.

7. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk? We would deploy our MA programs and infrastructure. These include our post discharge planning, comprehensive care centers, home care, claims accuracy programs, and our physician training/clinical flow programs.

We would c

The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking.

8. What are approaches for setting appropriate capitation rates?

There needs to be national and local benchmarks to adjust for the inherent geographic variation due to ethnicity, income, and hospital system concentration.

8A. What are the advantages and disadvantages of using national expenditure growth trends? The national benchmark tries to adjust and to reduce the local variation and create a more standardized approach to cost. There is a great deal of local geographic variation.

The nationa

8B. What about for using a local reference expenditure growth trend instead? Prefer to have CMS develop a mixture of national and local trend expenditure.

Prefer to ha

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.) There has to be risk adjustment. If the ACO population has a higher % of Duals, or if the top 5% of the population is exceptionally high cost, risk adjustment must be substantive. In original Pioneer ACO, one of our markets had Duals population >30%.

There has

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? There is compelling data that lower co pays for ambulatory visits for the PCP and specialists will reduce MLR. Lower co pays for medications prescribed to treat chronic disease will do likewise.

There is cc

10A. How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid? A great deal of work is still required on benefit and payment integration between of Medicare and Medicaid.

Great deal

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards? Clearly the ACO must be able to manage the risk and have the financial strength to bear the inherent variation of costs over a period of years. Patient identification and routing of claims are two major issues.

Clearly the

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

Patient and consumer education of all parties ? CMS, medical group, physicians, etc. Need strong actuarial input to assure comparability of the populations. Need CMS appeals line/compliance hotline.

Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries.

13. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology?

(•) Yes

( ) No

13A. What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution? Allowing patients to voluntarily align themselves with an ACO will promote greater patient engagement. There may be a risk for adverse selection.

Allowing pe

B. Integrating accountability for Medicare Part D Expenditures – An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes.

1. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?

No, Part D sponsors carry large membership population with each ACO to allow for meaningful utilization data to be shared with the ACO. The ACO would benefit from the whole data set from the pharmacy claims from every sponsor to gain a better picture of the population's health. Additionally, timely claims data from CMS would help with care coordination improvement.

1A. What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers? Reducing the co pays for the drugs for chronic diseases and getting data timely to the ACO to alert the ACO of refill rate.

Reducing th

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?

- (•) Yes
- ( ) No

2A. Why or why not? Obtaining the PBM data and adjusting the co pay would help achieve the goal for A & B utilization without taking on the full Part D risk.

Obtaining th

2B. If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method? The optimal drug management is best done with the prescribing physician and a consulting pharmacist at the local level to best understand the dynamics.

The optimal

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures?

- ( ) Yes
- (•) No

3A. What other mechanisms would allow ACOs to assume accountability for Part D outcomes? N/A.

N/A

C. Integrating accountability for Medicaid Care Outcomes – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations.

1. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

- (•) Yes
- ( ) No

1A. Why or why not? There is opportunity for quality and cost improvements as long as benefit and payment integration is aligned. Over time, this should be considered a requirement.

There is op

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? (For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?)

Those over 65, as those under 65 often have very different needs. The ACO should focus on 65+ year old beneficiaries.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?

The States should not disrupt current programs where Duals are receiving integrated care. Further encouragement of the development of an integrated care system should be taking place. There are some major Duals demonstrations where Federal ? State coordination is suboptimal for patient care and for taxpayer savings (e.g., CA Duals pilot) due to lack of payment and benefit alignment.

3A. What roles should States play in supporting model design and implementation? The State can help provide support in the integration of HIE. (e.g. Behavioral health and chemical dependency programs.) Additionally, immunization activities and done through the State should be made available through the ACO.

The State c

3B. Do States have adequate resources to support an ACO initiative in collaboration with CMS? Not the right blend of resources.

Not the righ

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?

If we can obtain the Medicare FFS and Medicaid FFS data timely in a method that we can incorporate into our current data systems. The severe data delays, at this point in time, are hampering our care improvement and performance.

4A. What are the capabilities of providers in integrating this data with electronic health records? Some groups have the ability with their data warehouse to incorporate claims data from labs, hospitals, and other vendors. Our EMR create actionable reports for the physician. We would benefit from HIE across all EMR platforms.

Some grou

4B. What are the capabilities of integrating information for care received in the community or from other non-traditional care providers? Uneven capabilities especially from non-traditional care providers.

Uneven ca

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? (Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?) Capitation. Benefit and payments would be aligned between Federal and States. This depends on many actions taken by CMS and State government.

Capitation.

D. Other Approaches for Increasing Accountability – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns.

1. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?

With the limited success of the ACO program, it would be premature to expand the scope. We should focus on what improvements are needed to the current ACO model.

1A. What are the most critical design features of a provider-led community ACO model and why? Physician and hospital alignment to the vision of the ACO.

Physician a

1B. What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Select those measures which would have the greatest impact on the population and the geographical area. (e.g. colon cancer screening, statin if a patient has CAD or DM).

Select thos

1C. Are there models to consider that better integrate community-based services beyond the traditional medical system? Will need to incorporate social service into the ACO model which best links community services with ACO and CMS services.

Will need to

In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives.

2. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?

- (•) Yes
- ( ) No

2A. More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments?

- (•) Yes
- ( ) No

2B. If so, what would the most critical features of such a "layered" ACO be and why? We need to understand the ETG proposal before a yes or no answer can be provided.

We need to

E. Multi-Payer ACOs – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs? It is easy to talk about multi payer ACO but that means that every payer has to agree to all the elements. (e.g. Quality gate definitions and threshold, etc.).

It is easy to

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden? CMS should move away from PQRS methodology to a pure claim based method in the immediate future to reduce the expense and cost side to the ACO.

CMS shoul

February 27, 2014

Patrick Conway, M.D.
Deputy Administrator for Innovation and Quality and CMS Chief Medical Officer
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, MD 21244

VIA ELECTRONIC DELIVERY AT: PioneerACO@cms.hhs.gov.

RE: Center for Medicare and Medicaid Innovation (CMMI): Request for Information: Evolution of ACO Initiatives at CMS

Dear Dr. Conway:

GlaxoSmithKline (GSK) appreciates the opportunity to submit comments on the Request for Information (RFI) on the Evolution of ACO Initiatives at CMS released by CMMI on Friday, December 20, 2013. GSK is a science-led global healthcare company that researches and develops a broad range of innovative medicines and brands. Our products are used by millions of people around the world. We have three primary areas of business in pharmaceuticals, vaccines and consumer healthcare (GlaxoSmithKline, 2013).

GSK supports the development and implementation of new payment and delivery models based on value and understands it is a crucial step in identifying innovative ways to provide greater accountability for both the delivery of quality and efficient care. In these emerging models, GSK supports the use of performance measures to encourage the provision of high-quality of care through adherence to clinical guidelines, improvements to care coordination and transitions, and to focus on patient decision making and patient experience of care. In regard to CMS's request for information, GSK supports the tenets of ACOs to provide better care for individuals, better health for populations and lower growth in expenditures but is cautious to support implementation of risk- based models where incentives to control spending could limit necessary access to services and medications, and may not be in the best interest of patients.

GSK believes that CMMI should take significant strides to ensure that the Pioneer ACOs demonstrate financial incentives for cost containment that are balanced by measures of health outcomes. Measures should be reassessed on a regular basis to identify new or remaining gaps to ensure that measures are maintained to keep pace with changes in technology and clinical practice. GSK feels strongly that CMMI should ensure that quality measures are added for clinical conditions where financial incentives are not balanced by quality measures, including identifying endorsed measures that can fill gaps and developing new measures where currently endorsed measures do not exist. GSK urges Pioneer ACO demonstrations to incentivize participants to reap savings through provision of better, more coordinated patient care rather than by creating incentives focused solely on cost of care. GSK feels it is imperative

that patients continue to have access to novel therapies, and that innovation is incredibly important to helping improve patient outcomes. Therefore, GSK believes it is necessary for CMMI to ensure that through these risk-based arrangements that incentives to create new therapies are not diminished by the lack of uptake by entities involved.

What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards (Section II (A), Question 11)

GSK believes that a potential area that may pose an integrity risk if ACOs transition to full insurance risk is related to the 340B Drug Pricing Program. GSK is concerned that if an ACO includes 340B covered entities, there may be a possibility that the ACO would seek discounted drug pricing for patients that do not meet the definition of a 340B patient. If the ACO inappropriately seeks access to the discounted drug price, this may undermine not only the integrity of the 340B program but also the intended goals of the Pioneer ACO demonstrations, and unintentionally create perverse incentives for ACOs looking to obtain an unfair advantage over other Pioneer ACOs.

Integration to Medicare Part D (Section II (B))

If CMMI includes Part D costs, GSK encourages that provisions are put into place so that patients must maintain appropriate access to treatment and services, where informed decision making by both patients and physicians is preserved. Within ACOs, it is essential that transparent information be given to patients to support broader choice for enrollees between ACOs. GSK also believes that patients should have access to a timely, transparent and affordable exception and appeals process, and that beneficiary protections are a crucial component to incorporating Part D expenditures into the Pioneer ACO shared savings model. Those protections should include and are not limited to: protecting patients' access to appropriate therapies through minimum formulary requirements, ensuring out of network access to appropriate therapies and securing sufficient broad participation among pharmacy networks to ensure convenient access to covered drugs.

Other Approaches to Increasing Accountability (Section II (D), Question 1)

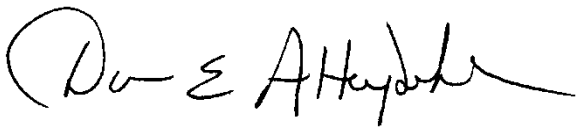
Because quality measures are such a significant component and a necessity for ACOs to participate in shared savings, GSK encourages CMMI to evaluate the current quality measures within the Pioneer ACOs and to encourage the adoption of outcomes based measures that improve health outcomes. GSK encourages the adoption of evidence-based measures endorsed through a transparent multi-stakeholder process (e.g. National Quality Forum (NQF)). GSK believes that evidence-based quality measures will help the healthcare system evolve from one rewarded for the volume of services to one promoting the value of services. Because medical advances occur rapidly, GSK encourages CMMI to evaluate and update quality measures on a regular basis to reflect the latest medical knowledge; continuous reassessment is required to avoid penalizing early adopters of care improvement and to facilitate medical innovations. If CMMI expands the ACO program to include a larger population, such as Medicaid where there is a distinct difference in demographic composition, health care needs, service utilization and spending; GSK encourages increased focus on complex chronic conditions, such as asthma and encourages the development and adoption of measures from prevention through diagnosis, treatment, hospitalization and maintenance of chronic disease. GSK recommends that CMS include measures focused on medication management, as this has been identified as a significant priority area for the Measure Application Partnership (MAP). Currently, there are several Pharmacy Quality Alliance (PQA) measures that have been NQF endorsed and could be included, these include (NQF#0546) Suboptimal treatment of hypertension in patients with diabetes and (NQF#0548)

Suboptimal Asthma Control; as well as measures that are NQF endorsed and are being utilized within the Medicare 5 Star program (NQF#0541) PDC for Diabetes, blood pressure and cholesterol.[1]

GSK also recommends inclusion of additional care coordination measures. Two measures "PQA Measure: MTM - Proportion of MTM-Eligible Members who Received a Comprehensive Medication Review (CMR)" and "Post Discharge Continuing Care Plan Transmitted to the Next level of Care Provider Upon Discharge" represent significant strides towards increased continuity of care and Comprehensive Medication Management (CMM).[2] GSK supports the improvement of CMM that is a continuous, systematic process used by providers to ensure patients' medications are coordinated, appropriate and understood by the patient. This population is a unique group of individuals; therefore, GSK believes ACOs should promote CMM as the standard of care. CMM should include assessing each patient's medications for appropriateness, effectiveness, safety and the ability to be taken as intended; developing a care plan that addresses any medication problems; follow-up evaluation of the patient to ensure outcomes are achieved; and communication with the patient's health care provider.[3,4] CMM measures are an important mechanism to ensure patients receive adequate care and providers appropriately manage patients with chronic conditions.

GSK appreciates the opportunity to comment on the Request for Information for the Evolution of ACO Initiatives at CMS. Please do not hesitate to contact me with any questions. Thank you for your attention to this important issue.

Respectfully submitted,



Donna E. Altenpohl
Vice President, Public Policy
GlaxoSmithKline

[1] http://www.pqaalliance.org/
[2] http://www.pqaalliance.org/
[3] Patient-Centered Primary Care Collaborative, "The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Outcomes." Resource Document: Available online at www.pcpcc.net/files/medmanagement.pdf
[4] U.S. Department of Health & Human Services. Multiple Chronic Conditions: A Strategic Framework: Optimum Health and Quality of Life for Individuals with Multiple Chronic Conditions. December 2010.nterventions to improve medication adherence in people with multiple chronic conditions: a systematic review. J Adv Nurs. 2008 Jul; 63(2):132-43.

From: Fortney, Cathy M. [mailto:Cathy.Fortney@AGG.com]
Sent: Friday, February 28, 2014 3:04 PM
To: CMS PioneerACO
Cc: Parver, Alan K.
Subject: Comments - RFI: Evolution of ACO Initiative at CMS
Importance: High

Good afternoon. Thank you for the opportunity to comment on *RFI: Evolution of ACO Initiative at CMS*. The following comments are submitted on behalf of the Healthcare Nutrition Council. Questions should be directed to Mr. Alan Parver at (202) 677-4900 or me at (202) 677-4956. Thank you.

Section I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?

Response: Yes

2A. Why or why not?

Response:

The Healthcare Nutrition Council (HNC) believes that suppliers of durable medical equipment (DME) and other DMEPOS items should be permitted to be included on the list of participating Pioneer ACO providers/suppliers. Generally, a Pioneer ACO should be able to include any and all types of providers and DME suppliers, including enteral nutrition suppliers, if the partnership makes sense in the particular marketplace and will help the ACO coordinate care for patients and achieve its goals. .

Enteral nutrition suppliers provide enteral nutrition therapy formula, supplies and equipment to patients. An ACO may decide to collaborate with an enteral nutrition supplier to more effectively coordinate care for medically complex beneficiaries, and to ensure that beneficiaries who can be treated in the home setting instead of hospitals and nursing homes will have ready access to such treatment. Patients require enteral nutrition therapy, otherwise known as tube feeding, when they are unable to take food orally. Enteral nutrition therapy involves a liquid formula administered by an enteral pump, syringe or gravity directly into a patient's gastrointestinal tract through a tube placed in the patient's nose, stomach or intestine. It is often medically necessary for patients with multiple, complex underlying conditions such as: cardiac disease, pulmonary disease, liver disease, pancreatitis, short bowel syndrome, inflammatory bowel disease, organ transplant, gastrointestinal fistulae, neurologic impairment, cancer, and critical illnesses. The provision of enteral nutrition in the home setting is less costly than when provided in institutional settings.

A Pioneer ACO may wish for an enteral supplier to participate in the ACO, and should be able to do so, because the provision of enteral nutrition therapy in the home can enable the ACO to coordinate

care and meet its cost and quality objectives. Patients treated with enteral nutrition therapy experience fewer complications, lower mortality rates and shorter hospitalizations as well as functional benefits and improved outcomes. As a result, home enteral nutrition therapy, when used appropriately and in a timely fashion, can contribute to lower health care expenditures. For these reasons, an ACO should have the discretion to allow enteral nutrition suppliers to be included on the list of participating Pioneer providers/suppliers.

Reference

National Alliance for Infusion Therapy and the American Society for Parenteral and Enteral Nutrition Public Policy Committee and Board of Directors, Disease Related Malnutrition and Enteral Nutrition Therapy: A Significant Problem With a Cost-Effective Solution, *Nutrition in Clinical Practice*. 2010; 25: 548-554.

D. Other Approaches for Increasing Accountability – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

1B. What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area?

Response:

HNC believes that malnutrition screening should be included in the quality measures used to assess ACOs. Establishing a patient's nutritional baseline and tracking subsequent changes can be enormously helpful in measuring whether the patient's health is improved through his/her interaction with the ACO. While CMS has acknowledged the impact of undernutrition (and obesity) on patient outcomes with the implementation of a body mass index (BMI) quality measure in the Medicare Shared Savings Program, patients may be malnourished regardless of BMI as they may be deficient in the macro and micro nutrients needed to help promote healing and reduce medical complications. Providers can mitigate the negative impact of malnutrition by routinely screening individuals to identify malnourished patients and patients at risk for malnutrition, and providing patients with follow-up assessments as well as timely interventions where indicated.

The presence or absence of malnutrition is not always obvious, and the prevalence in all care settings is alarming. For over 30 years, large-scale studies have shown that as many as half of hospitalized patients and 35% to 85% of older long-term care residents are undernourished. In the community setting, poor nutritional status is present before disease appears, as is risk of malnutrition. Malnutrition often is associated with acute and chronic diseases and injury; certain diseases, such as cancer, stroke, and chronic obstructive pulmonary disease may cause a person to be unable to ingest or absorb nutrients, require more energy, or become undernourished due to dietary restrictions. Nutrition status is also associated with the social determinants of health and poor nutrition can be linked to health disparities.

The severe consequences of malnutrition include:

- Increased morbidity and mortality;
- Longer hospitalizations;
- An increased likelihood that patients will be readmitted to a health care facility or will require ongoing services; and
- Higher health care costs.

Identifying and monitoring patients at risk for malnutrition as well as malnourished and undernourished patients, and then providing them with timely, medically indicated clinical treatments, can significantly improve an individual's health and reduce preventable death, disease, and disability. Based on the results of the nutrition screening and assessment instruments, providers can establish appropriate treatment plans and offer patients effective treatment options. These simple, low-cost activities can produce measurable improvements in a patient's health.

For these reasons, we believe that CMS should include malnutrition screening and nutrition intervention for patients identified as at-risk as quality measures, thereby encouraging ACOs to screen and assess their patients for malnutrition, undernutrition and the risk of malnutrition and furnish them with appropriate, cost-effective, clinically-effective treatment.

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Arnall Golden Gregory Selected for *The National Law Journal's* 2013 'Midsize Hot List'

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TO: Centers for Medicaid & Medicaid Services, HHS

FROM: Timothy Ford, EVP, Health-Lynx, LLC
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Piscataway, NJ 08054
(732)562-7805
tford@health-lynx.com

DATE: March 4th, 2014

RE: Submission Regarding the Request for Information (RFI), Evoluation of Accountable Care Organization (ACO) Initiatives

Cut and Pasted into CMS's online submission (2/28/2014):

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

Both the Pioneer program and the MSSP have been successful in increasing the number of providers and provider organizations participating in the transformation of health care delivery and financing. Some organizations were created solely in response to these new programs. Others were established prior to the ACO programs but through their participation in them have intensified their commitment and resources to transforming their activities.

We believe that CMS should continue to focus on creating opportunities that increase the number of providers participating in ACOs and therefore transformation activities. The cultural transformation of the healthcare system is integral to the delivery and financing transformation. Cultural change will be enhanced by having more providers engaged in the process.

Our overall comments reflect recommendations which will encourage broader participation by providers in ACOs. As such we strongly oppose program changes which will push providers to accept risk beyond their current capabilities to manage successfully The performance of the Pioneer ACOs and the MSSPs while extremely promising is also testament to the fact that many would fail if required to accept too much risk before they have developed the competencies to manage the risk. It should also be noted that there is financial cost to developing those competencies. It is important that a learning path be developed that allows for the development of skills while embracing increasingly more risk.

Regarding the Pioneer ACO program specifically we believe most provider organizations that are serving the general Medicare beneficiary population will be more interested in participating in the MSSP than the Pioneer ACO program. The main reason for that is the regulations are fixed and transparent. Also, since this program is being widely implemented by provider organizations there are greater opportunities for learning and the application of successful practices from other MSSP organizations. In addition, the

managed care services industry is continually developing products and services specifically targeted to support the MSSPs.

Some provider organizations however may want to serve specific segments of the Medicare population. They would benefit from the ability to propose non-standard models that incorporate more innovative delivery and financing features for specific Medicare populations. The CMS will need to use methodologies that only attribute specific populations to them. The Pioneer ACO program can be the vehicle for implementing unique programs around specific population segments.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

The Pioneer ACO program should be a vehicle for the beta testing of new approaches. Given our above comments we think that the Pioneer ACO program should encourage the greatest degree of flexibility in serving Medicare beneficiaries. The continued administration of a competitive application process rather than the application of qualifying criteria as used in the MSSP is more appropriate. Each application should be reviewed on its innovativeness and merits.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

We believe the key to this program is to have minimal restrictions other than those necessary for protecting beneficiaries' safety and rights. The Pioneer ACO program should be the source for beta projects including the testing of different payment models. Applicants should be allowed to offer their own recommendations for new payment models which can then be reviewed by CMS for appropriateness and the ability to implement. Aligning with our general comments posted at the beginning however we think it is important not to require organizations to take downside risk initially.

B. **Population-Based Payments:** CMS allows Pioneer ACOs to transition to population -based payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS 3 revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a 40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer

providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

Yes. Part of the evaluation for improving care and lowering cost is to create effective opportunities for the substitution of different services. Being allowed to choose different FFS reduction amounts allows an additional tool in tracking accountability and effectuating optimal care delivery.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

Yes. DME equipment should not be required to be part of reduced FFS payments but if the ACO applicant believes that reducing the FFS payment and impacting the utilization of DME is an integral part of their strategies there does not seem to be any basis for its exclusion.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

No. Given that less than half of the initial Pioneer ACOs created statistically significant savings it does not seem prudent to allow an organization to receive PBPs before they have demonstrated the ability to manage risk and generate a specified level of savings.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

No additional comments.

Section II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:

• Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;

• Give providers more tools and resources to improve care outcomes and efficiency; and

• Continue to preserve beneficiary freedom of choice in FFS Medicare.

CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

A. **Transition to greater insurance risk** –ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues.

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

We do not recommend this step at this time. First, as noted there are Medicare Advantage plans available in most markets that often give opportunities to ACO providers to assume insurance risk. Second, American Academy of Actuaries briefs and work published by CMS have highlighted the specific actuarial risks around smaller populations. The article "Statistic Uncertainty in the Medicare Shared Saving Program" published in 2012 highlights the probability of incorrect outcomes for smaller populations in particular but even for larger populations. These same risks would translate to capitation payments. Also, ACO provider organizations will typically not have the same financial resources or skills for managing risk as insurance companies participating in the Medicare Advantage program. Third, it is unclear that true insurance risk can be assumed in the absence of an ACO's ability to establish access to care requirements or obligations for beneficiaries. We do believe that CMS should allow ACOs to establish voluntary programs for beneficiaries that could establish conditions before attribution to the ACO. These voluntary programs would not impact beneficiaries' fundamental traditional Medicare freedom to select providers and services of their choice. These program however could incentivize them to cooperate with initiatives that improve their care and/or may lower their out-of-pocket spending.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

We do not recommend that the standard program require taking risk beyond Medicare Parts A and B. There is great interest by providers in integrating Medicare Part D into the ACO proposition. It comes however with potential pitfalls. Namely, while the Part A and Part B program are relatively standardized in terms of service units and price the same is not true for Part D. Each Part D supplier maintains different formularies, drug tiering, and pricing. Unless ACO providers could limit their involvement to a single Part D plan and receive full transparency into utilization and cost it is difficult to believe that the conditions to accept risk exist. If CMS could find a way to address these issues than Part D incorporation could be re-considered.

We are also insufficiently convinced that taking risk for Medicaid and Medicare for dual eligible is feasible at the individual ACO level. Medicaid programs vary by State. From our perspective any

initiative that involves Medicaid must also involve active involvement by the applicable State. We therefore believe that initiatives for dual eligibles should not be initiated for individual ACOs absent input and participation by the applicable State.

3. Are there services that should be carved out of ACO capitation? Why?

We are not convinced that services should be carved out of risk bearing payments to ACOs. The ACO should maintain focus on the whole person and the whole dollar. Carving services out would have the potential for creating potential dysfunctional care decisions. The question however seems to allude to the potential general danger of assuming risk. Our recommendation is that rather than looking at service exclusions, that CMS consider increased opportunities for sharing risk for catastrophic patients beyond those seen in the Pioneer ACO program and the MSSP.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

It is difficult to contemplate these type of agreements other than allowing ACOs to develop voluntary programs which may include compensation to non-ACO providers who agree to coordinate care on behalf of the ACO patients. The application of involuntary programs could impose potential threats to a traditional Medicare beneficiary's freedom of choice of providers and services.

5**. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk?**

As long as ACO beneficiaries are maintaining their freedom of choice of providers and services then certainly the access and most of the member services regulations applicable to Medicare Advantage would not be appropriate for the ACO beneficiary population. For the same reason, many of the Medicare Advantage marketing/communication regulations would not be applicable. The communication rules should hew pretty closely to those already in effect for Pioneer ACOs and MSSPs. Reserve and risk bearing financial requirements have traditionally been under the State rules where the Medicare Advantage plan operates. These requirements are unlikely to be different for ACOs assuming full insurance risk unless CMS intercedes on their behalf.

6. **What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?**

We would recommend that CMS work with the NAIC to provide standardized guidelines that states could adopt that would provide a pathway for ACOs to take insurance risk for Medicare FFS beneficiaries. The current waivers currently in place for the MSSP should be applied for ACOs taking on full insurance risk as the same issues apply.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

Most ACOs have emphasized care management infrastructure development. If they move to taking full insurance risk they would need substantial development of insurance support infrastructure. The vast majority of ACOs would need to significantly improve their financial reporting systems to accommodate taking insurance risk. Complimentary to the financial reporting they would need substantial build out of actuarial resources particularly if they were to undertake a bidding process like that used by Medicare Advantage organizations. In addition they would need to build attribution tracking that more closely resembles membership management tracking utilized by insurance entities.

We find that most ACOs are building infrastructure that supports better care coordination and collaboration at point of service when care is delivered. The deployment of EMRs to improve care is a prime example of that effort. ACOs however also need to take in population health which involves taking the widest scope of perspective on beneficiary needs. Providers need to understand, obtain, and deploy the tools of population health. It is our finding that most ACOs need to improve their development and use of population health analytics.

Last, most ACOs would like likely need to invest more in direct care management resources, such as nurse care managers, if they are taking on full insurance risk.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

Establishing a blend of national and local expenditure growth trends would be conducive to creating the broadest level of geographic participation.

9. What are the advantages or disadvantages of different strategies for risk-adjustment?

(Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

Risk-adjustment is foundational to creating a transparent and successful ACO program. We strongly recommend however that CMS use a single risk adjustment model across all CMS programs and that it be deployed identically throughout all programs including the Medicare Advantage program. Without that transparency and consistency providers will not develop an understanding of assessing patient risk.

10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

Given that ACO beneficiaries are still exercising their freedom of choices of providers and services a principal tool for ACOs to conduct effective patient engagement will be the application of benefits enhancements. We would recommend that ACOs be given the right to propose any type of benefit enhancement for its attributed members and that CMS be liberal in approving them. It is important that ACOs demonstrate their benefit to beneficiaries and enhancements can be a major tool for doing so. While we do not propose any preliminary restrictions it is uncertain to us how enhancements could be implemented for Part D or Medicaid services.

11. **What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?**

Please see the response to Question 5 above.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

Please see the response to Question 5 above.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

Our experience from working with non-Medicare populations is that there can be significant variance between the primary care physician that a member identifies initially and the primary care physician that they would be assigned based upon a claims based attribution methodology. Similarly our experience with MSSPs has shown that there is significant turnover in quarterly attribution. Given these observations it does not seem prudent to make self-alignment available to any Medicare beneficiary. Our recommendation would be to make ACO beneficiary alignment only available to those who would have been assigned to that ACO based upon an attribution methodology. Throughout the course of a performance year there should also be criteria established for removing beneficiaries for attribution, i.e. they move out of the area.

B. **Integrating accountability for Medicare Part D Expenditures**– An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

Part D services are essential part of a beneficiaries overall health and quality of life We encourage CMS to identify ways that would allow ACOs and Part D suppliers to work clinically and financially together.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume

accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

Allowing ACOs to accept Part D risk only with Part D suppliers with whom they have established a relationship would be a viable approach to integrating Part D risk into the ACO program.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

Most PBMs that offer Part D plans have real-time clinical and dispensing information available to providers. We would recommend that CMS require that the ACO and ACO primary care providers be electronically connected to these information services as a condition for accepting Part D risk.

C. **Integrating accountability for Medicaid Care Outcomes** – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

Yes. Assuming that the Medicaid outcomes have been defined sufficiently in advance. Given that the ACO program is voluntary those ACOs that are uncomfortable assuming accountability would not participate.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

ACOs should have options to serve both general or sub-sets of the dual eligible population. The availability of options will increase the opportunities for innovation.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

It is preferable if CMS collaborate with States to define opportunities that are available to any willing and capable ACO organization within the State.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

All ACOs to some degree have developed the capacity to integrate data from different clinical and claim sources. To date a significant problem has been exchanging information with non-ACO providers. This is particularly important as ACO beneficiaries have freedom of choice and they may be utilizing both ACO and non-ACO providers. Many states however have functioning Health Information Exchanges that can connect all providers. They are the preferred vehicle for delivering and exchanging electronic health record information as well as claim information.

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

This would seem to be best addressed on a State-by-State issue basis based upon the local program considerations that exist.

D. **Other Approaches for Increasing Accountability** – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

In general, this approach would seem to be very difficult to apply in urban areas where there are multiple providers.

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

CMS currently makes these assessments in determining when programs are competitive and where they may be complimentary. The current guidance seems to focus on whether the same group of dollars are at

risk in more than one program. We recommend continuing that approach with a guiding principal that any payment initiatives be transparent to all applicable providers.

E. **Multi-Payer ACOs** – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

While there is room for downstream payment initiatives like bundled payments we would encourage CMS to focus on initiatives that are based upon total dollar expenditures. As noted earlier, ACOs goals should align around the total person, the person's entire health care experience, and the total dollars in expenditures.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

The cost of quality metric collection is significant and often not the best use of resources which could otherwise be dedicated to direct care management or quality improvement. For example, it is our observation in the MSSP program that while a measure by measure case can be made for the individual metrics selected, that the cost of applying what are often non-standard measures has resulted in significant collection expense. We estimate that 500 to a 1000 man hours, depending upon the ACO, are required to complete the annual data collection. As a general principal we believe that the greater the reliance on claims derived measures the lower the cost of collection. The NCQA HEDIS measures are the leading example of claims based measures. Many EMRs can now collect and submit quality measures based upon clinical records rather than claims. The processes for those measures however need to be built within the EMR as they often involve a smart logic. That EMR development should be encouraged through the promotion of measures that would be applicable across multiple players. What should be avoided except where a true exception exists is to require reportable measures that are non-standard and cannot be routinely collected from claims or EMR data.

CMMI RFI: Evolution of ACO Initiatives at CMS
Hennepin Health Response

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes based contracting. The Model is now entering its third performance year with 23 organizations. In addition to increasingly aggressive risk arrangements, CMS offers eligible Pioneer ACOs the opportunity to transition from fee-for-service payments to monthly population-based payments to give these organizations more revenue flexibility in determining how to best motivate providers to improve quality of care and reduce costs for their patient populations. As more and more health care organizations begin to hone their skills in care coordination and engage in outcomes-based contracting, CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

    - CMS ACO models would be more attractive if they included Medicare Advantage and Medicaid beneficiaries in addition to traditional Medicare. This would allow participants to align strategies across these coverage groups and achieve a "critical mass" of patients for whom total cost of care rather than fee for service is the dominant payment model.

B. **Population-Based Payments:** CMS allows Pioneer ACOs to transition to population -based payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer

providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a 40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

Section II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:

- Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;
- Give providers more tools and resources to improve care outcomes and efficiency; and
- Continue to preserve beneficiary freedom of choice in FFS Medicare.

CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

A. **Transition to greater insurance risk** –ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would

encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues.

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

    - Yes. Full-risk capitation with a prospective enrollment model is the desired approach in order to maximize flexibility and rapidly improve outcomes.
    - However, this must come with some ability to define provider networks and manage care within a specified group of providers.
    - There is undoubtedly friction between beneficiaries' freedom to select any provider and the goals of improving outcomes through ACOs.
    - CMS should seek a middle ground through which certain levels of choice and access are retained while ACOs have some ability to drive utilization to a defined group of participating providers.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

    - All of the above.

3. Are there services that should be carved out of ACO capitation? Why?

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk?

    - As a Medicare Advantage plan, Metropolitan Health Plan (a partner in Hennepin Health) is subject to a number of regulatory requirements that do not add clear value to ACO models. CMS should consider streamlining certain requirements. In particular:
        - Model of Care requirements are substantial but have little connection to positive measureable outcomes
        - There is a great deal of duplication in the required reporting
        - The requirements don't capture the Social Determinants of Health in a meaningful way.
        - The sheer volume of requirements is overwhelming

  - The Star Ratings don't account for small enrollment plans. Some ratings need a minimum number of responses in order to score them.
  - The requirements are not tied to outcomes.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

   - Many ACOs would be challenged to meet state requirements around financial reserves and capitalization, as well as member services.
   - Absent major changes to the regulatory framework to license ACOs as risk-bearing entities, ACOs would likely need to acquire managed care functions or align closely with a managed care organization partner under a third party administrator-like arrangement.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

   - ACOs would need to develop (or contract for) the following infrastructure components:
     - Provider Contracting
     - Network Management
     - Claims Payment
     - Member Appeals and Grievances
     - Regulatory Reporting Requirements (financials, quality measures, etc.)
     - Warehousing and Analysis of Administrative (i.e. claims) Data

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

   - It is crucial that CMS ACO efforts not systematically disadvantage ACOs in regions of the country that have historically operated more efficiently. In most cases, benchmarking based on national trends is most appropriate.

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

- It is important that risk adjustment include measures of the social determinants of health. Recognizing the social and economic context of the population is particularly important for Medicaid patients.
- [*Nancy will likely have many good comments here given her work with NCQA in this area.*]

10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

    - ACOs at full insurance risk would likely incorporate the principles of Value-Based Insurance Design, including selective reduction or elimination of cost sharing for services tied to favorable outcomes
    - ACOs would also offer "value-added" services not traditionally covered by insurers. In the Medicaid context, this would mean investments in housing, job supports, and other services with a strong evidence base linking them to health care utilization and outcomes.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

    - It is important that CMS' ACO initiatives evolve from reliance on claims-based attribution to a prospective enrollment model.
    - The experience of Hennepin Health (Hennepin County's Medicaid ACO project) has shown that some of the sickest and costliest Medicaid patients are those who are not connected to primary care – those largely left out of current CMS ACO models.
    - Moving to an enrollment model creates an important incentive for ACOs to perform outreach into their communities and establish community relationships to improve outcomes.

B. **Integrating accountability for Medicare Part D Expenditures**– An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

C. **Integrating accountability for Medicaid Care Outcomes** – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

    - Yes. It is crucial that ACOs achieve a "critical mass" of patients for whom total cost of care rather than fee for service is the dominant payment model.
    - Further, including Medicaid has tremendous potential to simplify the administration of ACO arrangements (e.g. common quality measurement approaches, financial analysis/reporting, contracting, etc.).

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable

for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

- CMS and participating ACOs should enter into arrangements with the goal of accountability for the broadest possible population across Medicare and Medicaid.
- CMS should offer flexibility for ACOs to target sub-populations like those listed above for initial inclusion, but should encourage expansion to other populations explicitly.
- Defining populations geographically has a lot of potential to improve outcomes on a large scale, incenting local/regional collaboration and ensuring that high-priority populations cannot "slip through the cracks" of visit-based attribution methodologies.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

- The experience of Hennepin Health has shown the importance of strong state partners in implementing a Medicaid ACO model.
- States are necessary partners in bringing Medicaid into CMS ACO models, as they hold the administrative data needed to measure cost and quality and perform risk adjustment.
- States can function as conveners to ensure stakeholder participation in model design, ensuring that state-specific circumstances are considered.
- States could play a central role in feeding Medicare and Medicaid data to ACOs.
- States are likely to need additional resources to support an ACO initiative in collaboration with CMS, including staff time, resources for data analysis, and contracting support.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

- The State of MN has already done considerable work to integrate Medicare and Medicaid data through its integrated managed care products for dual-eligibles and it all-payer claims database.
- However, these data largely exist in databases and reports that are disconnected from electronic health record systems.
- Aligning data feeds across Medicare and Medicaid would increase the likelihood of ACOs integrating data into electronic health records and using administrative data to improve care and manage populations.

- Hennepin County and HCMC have made considerable strides in integrating health care and social services information into its shared electronic health record, including comprehensive assessments of social and behavioral factors, housing information, and case management. However, this "proof of concept" has been done on a relatively small population enrolled in its Medicaid ACO product. Expanding such approaches population-wide would require the development of data standards and connections between social services systems and electronic health records.

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?
   - Like its current shared savings and Pioneer options, CMS should continue to offer both shared savings and greater risk-bearing approaches (such as capitation).
   - They key factor is that CMS unify the arrangement with any one ACO to include both Medicare and Medicaid. To do otherwise would lead to duplication of effort at best, and conflicting approaches at worst.

D. **Other Approaches for Increasing Accountability** – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

   - These concepts are being actively explored through MN's SIM efforts, and are crucial to the future of health care improvement.
   - Except in markets with a single dominant provider/delivery system, a geographically-based model must include a level of governance or organization binding multiple delivery systems together around common goals.
   - The structure of Oregon's Community Care Organizations offers a possible model to emulate.
   - Outcome measures should include community-wide public health information that would create incentives to engage in prevention and address the social determinants of health in deliberate ways. This measurement approach would likely need to extend beyond a one- or three-year performance period.

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

   - Whether formalized or not, CMS should allow (and in some cases encourage) participation in multiple reform initiatives wherever possible. In the past, states and organizations have missed out on the opportunity to participate in valuable Medicare demonstration projects because other demonstrations were already in place.
   - Generally speaking, CMS should be less prescriptive about service delivery models as organizations assume more financial risk. Evaluation approaches should closely examine what has been effective in achieving favorable outcomes, but participant organizations should not be required to follow a set sequence or choose from a menu of specific care delivery or payment components if they are at or near full-risk.

E. **Multi-Payer ACOs** – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

   - The most direct opportunity for CMS to encourage the adoption of ACO contracts among multiple payers is through the private health plans administering Medicare Advantage and Medicaid.
   - CMS (and states) can also encourage the adoption of ACO contracts by supporting the use of all-payer administrative data and health information exchange (HIE). The availability of readily-available, payer-agnostic data to drive care improvement and lower costs would dramatically lower the administrative barriers to provider systems managing multiple aligned ACO contracts and trying to reconcile multiple data feeds and reporting streams.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

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Center for Medicare and Medicaid Innovation Request for Information: Evolution of ACO Initiatives at CMS

Section I: Additional applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. Input on the level of interest for CMS to open second Request for Applications for the Pioneer ACO Model

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

- For organizations not currently participating in the Pioneer program, the most attractive strategy may be to wait until a body of experience grows about the current program. If there is no clear incentive to adopt this form of risk-based payment now for those organizations, then a second RFA round using the same basic program parameters is not likely to be attractive. There is a strong incentive to wait for the original set of organizations to test the Pioneer model and find out what works/doesn't work.

  At this point, the lack of detailed, explanatory results from the first year of the Pioneer ACO model may deter others from applying -- there is little known about whether the organizations working in the current model are effective at managing risk and saving money. The CMS-released Pioneer ACO results were inconclusive and did not explain what ACOs were doing to effectively (or not effectively) manage their patient populations. This is important because participating organizations are businesses functioning in an uncertain and changing healthcare marketplace and most have many patients in addition to the Medicare population.

- Any data on "savings" will have to clearly separate and report on savings to CMS and savings to the participating organization. Lowering Medicare payments and saving CMS money is one type of savings; internal savings net of program costs is another. None of the preliminary data on Year 1 of the Pioneer program spoke to the question of the participating organizations' balance of operational costs, revenue losses, and shared savings payments to program participants.

- Recent studies have suggested that CMS had substantially underestimated the start-up cost and the first year operating expense of an ACO. Without a realistic understanding of this initial cost of implementation, establishing an ACO would be a

risky decision to make. Again, the decision to participate is a business decision and involves business considerations like investment, profit and loss.

- The label "Pioneer" will be less appropriate as time goes on and experience grows with the current Pioneer model, the Shared Savings Program, and private-sector ACO initiatives. There may be interest in applications for a program with the same parameters as the current Pioneer program, but those participating in it would no longer truly be "pioneers".

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

    - CMS should limit the number of selected organizations, because of the status of the Pioneer program as a formal demonstration project. The criteria for participation should include willingness to participate in formal evaluation activities (and funding to support that participation) and willingness to have a variety of financial and quality of care performance measures publicly reported.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

    - One change to the current Pioneer model that would attract additional applicants and still retain the core, essential features of the current model is a more attractive set of financial incentives. But significant changes in that direction would, at some point, involve a test of a different model, not an expansion of the original model. Alternatively, participants might be offered the option of measuring their success against local area per capita costs rather than using year to year comparisons of their own costs.

    - The current patient attribution approach (an "open network") and the claim data availability (accurate data only available after end of year) make it difficult for ACOs to track utilization and expenditure data which would have been critical to address specific needs of defined ACO population; they also make patient engagement activities difficult. More frequently-released claim data will be most helpful for ACOs to design target programs to control costs. Alternatively, participating organizations might be offered the option of signing up patients who would volunteer to receive all of their care from the ACO for a period of one or several years, since many Medicare patients tend to receive most or all of their care from the type of organization (group practice based entities) anyway.

B. Population-Based Payments

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

    - Yes. It would be of importance because potential cost savings in ACOs will come from reductions in use of elective services, therefore the burden of lost clinical revenue will not fall evenly on all types of providers. A very successful ACO might have large reductions in Part A payments but no reduction, or even an increase, in Part B payments. Such an ACO may wish to have a large reduction target for Part A and no reduction, or at least a smaller reduction, in Part B. Hospitals, procedural

specialists, radiologists, and home health care agencies are likely to see volume and revenue decreases in successful ACOs. Primary care physicians and specialists providing overall care management and coordination for patients with chronic diseases may see payment increases, particularly if CMS FFS payment models include new and specific payments for care coordination activities. In order for the ACO to be successful, these physicians need to continue care management and there needs to be enough revenue to support costs of other care management staff. The entity may incur some expense in setting up and sustaining care coordination functions, but they will generally be providing more of what ACOs will be expected to provide. The demonstration model will be successful it it recognizes the different incentives of various types of providers, acknowledge those competing incentives, and focus ACO development on those providers whose activities are most likely to grow, rather than shrink, under more efficient care patterns.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

    - If CMS intends to support the concept of health system integration, then they should include hospital-owned DME suppliers on the list of Pioneer participating providers. With this alignment of services, incentives for all business units within an ACO can be better aligned to reduce cost and improve quality. Therefore, some of the current competitive bidding rules for Medicare DME providers will have to be waived in order to give ACO management a degree of control over service and incentive alignment for Medicare patients, similar to the integration allowed by private insurers for non-Medicare patients. The ability to manage and be accountable for every aspect of care, including DME services, is essential to an ACO's success. While beneficiaries continue to have a choice of providers, ACOs, barring rule changes, will be limited to choose from only those DME providers who have been successful in the larger competitive bidding process. These unaffiliated Medicare DME suppliers do not share the ACO's goals or bottom line. Hospitals and integrated health systems that currently use their own hospital-based DME companies have a greater ability to align services and incentives because all business units are housed within one system. The competitive bidding rule is problematic because it disrupts this tight integration across business units for the Medicare population. For other patients of the entity, DME is often tightly integrated into the hospital discharge process and other home-based services in ways that prevent readmissions, ER visits and unnecessary SNF days.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

    - If ACOs are going to receive PBPs and be responsible for providing needed clinical services from those payments, then some insurance-like financial reserve requirements should be in place. Generating savings in one or two previous years does not guarantee savings in future years and makes it marginally harder to achieve savings later. Also, "savings", is not the same as financial stability if "savings" means savings to CMS but not overall savings net of program costs for the ACO. An ACO's financial stability could be endangered while still producing "savings" for CMS in previous years.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

    - CMS should consider inclusion of a specific care coordination or care management payment made on a per-beneficiary per-month basis, as is currently done in some of the primary care medical home demonstrations.

Section II: Evolution of the ACO Model

A. Transition to greater insurance risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

    - Evolution of the ACO model should preserve the crucial conceptual and legal distinction between insurance organizations and health care provider organizations. Organizations receiving capitation payments are effectively functioning as insurance companies and should be labeled as such and subject to applicable financial reserve requirements and state insurance regulation. Full capitation models and partial capitation models both involve some historical negative "baggage" from experience in the 1990s under the managed care label. Neither physician groups nor hospitals are naturally well-positioned to manage capitation, and both involve incentives to provide fewer services or limit access in ways that eventually have the same effects on hospital and specialist revenues as described just above in the shared savings model. Some form of capitation payment removes the immediate possibility of providers simply increasing volume of services to increase revenue, but has the negative effect of putting the combination of physicians and hospital(s) at risk for incidence of disease or injury that they cannot control.

    - If CMS does move in the direction of full capitation for ACOs, distinctions between ACOs and Medicare Advantage plans will be lost. CMS already has a policy and payment option in place that involves full capitation payment for a defined population – Medicare Advantage.

    - Exceptions can be made for limited risk models that are a form of bundled payment, such as the inpatient DRG payment which bundled a desired set of services and assigned a standardized payment. Or, if limited risk in the form of partial capitation payments only applies to clinical services within a specific domain – for example, a partial capitation payment to a cardiology group for provision of cardiology services -- these would not have to be subject to insurance regulations, since the members of the group themselves can provide the required clinical services without paying an outside entity or witholding care to meet financial goals. Capitation payment to an ACO by CMS or a Medicare Advantage plan is an option, but is inevitably difficult, given that hospitals and physicians are in the business of attracting the sickest patient (bad risk) and have limited ability to attract healthier patients to help offset costs for patients needing the most care. Any global capitation should be subject to insurance regulation, including reserves, risk adjusting and formal enrollment.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

- Per comment immediately above, putting ACOs at full insurance risk is not a good idea, regardless of the categories of spending included in the capitation model.

3. Are there services that should be carved out of ACO capitation? Why?

    - See response to question 1.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

    - See response to question 1.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk?

    - See response to question 1.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

    - This will vary from state to state – it seems likely that many state insurance commissioners would not allow ACOs to function as insurance companies unless they went through the process of becoming licensed and approved as insurance companies. Many integrated health systems own an HMO or insurance company which they can use to meet insurance regulatory requirements. However, the whole point of the ACO would seem to be to find a way to install all the restraint of predetermined payment characteristic of insurance into delivery system payment as an alternative to fee-for-service. The ACO is an opportunity to model partial capitation and bundled payment arrangements that are neither insurance nor fee-for-service.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

    - See response to question 1. To manage insurance risk, ACOs would have to essentially become Medicare Advantage plans. If state insurance commissioners decided that full capitation risk makes an entity effectively an insurance plan and subject to that body of licensure and regulation, there will be no difference between ACOs and Medicare Advantage plans.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

    - A bidding process similar to that used for Medicare Advantage should be employed if this general direction is followed at all, with no particular assumptions made about expenditure growth trends. Some entities might be offered the option to

accept a rate that results from a competitive bidding process in a type of "any willing provider arrangement."

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

    - Demographic factors like poverty, illiteracy, limited English proficiency, and absence of social support are all directly linked to poor health outcomes. Patients with one or more of these characteristics as they enter Medicare are less likely to have had adequate insurance or medical care before age 65, and therefore carry a more extensive burden of illness into the Medicare years. ACOs will have a clear incentive to avoid such patients if outcome measures used to evaluate performance and calculate shared savings payments are not adjusted in some ways to take these factors into account. ACO risk adjustment models, either for quality metrics or for many forms of provider payment, including capitation, should include demographic factors other than age and gender, (e.g. poverty, illiteracy, limited English proficiency, lack of social support) because they are known to have an influence on health care utilization and costs. Even though these social/demographic variables are typically not found in claims data and may be difficult to find in chart reviews, proxies may be found in census data that can be linked to patient address information. A more robust and fair risk adjustment model can and should be developed for future ACO models. Absent adjustment of one type or another, ACOs and their participating providers will have a clear and perverse incentive to avoid treatment of patients at relatively high risk for utilization and costs.

10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

    - Aligning patient incentives so that patients choose to seek care within a single ACO and comply with medical directives will have important implications for the ability of ACOs to reach their cost-saving and quality goals. To add some financial incentives for beneficiaries to participate ACOs can offer reduced or waived co-pays as well as credits/discounts for health care services for completion of health risk assessments or improvement on health risk scores. The assessments will enable an ACO to identify patient needs and monitor a patient's adherence and progress.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

    - See response to question 1.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

    - See response to question 1.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned

beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

B. Integrating accountability for Medicare Part D Expenditures

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

   {No comment}

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

   {No comment}

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

   {No comment}

C. Increasing accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

   - The issues of Medicare and Medicaid patients' participation in ACOs are separate, except for the special case of the dual eligibles. Besides the dual eligible population, there is no essential connection between the two. An ACO with an attributed Medicare population of adequate size may not have an adequate Medicaid population, and vice-versa. The population and clinical issues in the two populations are significantly different, with a focus on diseases of the elderly for Medicare and diseases of young women and children for Medicaid. There would be no fundamental reasons why a Medicare ACO could not also be a Medicaid ACO, but the one does not imply or require the other. Some care coordination and population management infrastructure may be common between the two sets of patients, and there may therefore be some economies of scale for organizations functioning as an ACO in both programs. The populations and providers are enough different, though, that no blanket policy encouraging involvement in both Medicare and Medicaid would be warranted.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-

Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

- The dual eligibles are a natural priority population for CMS and ACOs. This would be most clearly true for the dual eligible over age 65, but would also be true for those under 65 who have Medicare coverage due to disability. Some special risk adjustment models and payment adjustments would have to be made, though, for including dual eligible under age 65 whose costs will generally be higher than the Medicare average due to the presence of the disability that led to eligibility.
- It is advisable that ACOs have choices of specific subgroup(s) among the dual eligibles that the ACOs would be accountable for. For instance, an ACO specialized in behavioral services is more experienced with young duals with mental illnesses, but may not be good at managing care services of an older cohort that needs more institutional care.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

   - ACOs are one particular type of integrated care system; policies that encourage development of ACOs do not necessarily encourage the development of other types of integrated care systems. In general, payment reforms that move from fee-for-service models to more bundled approaches encourage the development of integrated care systems, as those systems are more naturally suited to the provision of coordinated episodes of care. State laws restricting the employment of physicians serve as a barrier to integrated systems built around an employed physician model could be changed. State laws about scope of practice for non-physician providers can restrict the roles of providers like nurse practitioners in integrated systems – those could be changed. States that have managed care models for their Medicaid programs have already outsourced major care management and cost management functions; they could encourage managed care plans in their Medicaid programs to contract with integrated systems as preferred care providers.

     Integrated care systems do not necessarily have to have a common ownership and management structure nor employed physicians; states and the federal government can streamline HIPAA and other regulatory barriers to exchange of clinical information among providers and encourage IT and telemedicine initiatives that involve clinical information exchange among otherwise independent providers.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

- In an era of electronic medical record systems, ACO providers generally have reasonable access to information within their own system and have limited or no access to information about care outside their own system. "Outside" can include care provided in the community and by non-traditional providers as well as care paid for in Medicare or Medicaid FFS but outside the organizational boundaries of a particular electronic medical record system. ACOs and their participating providers generally have no access to Medicare or Medicaid claims data sets or reports derived from those data sets.

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

    - There are reasonable things to do with any and all of these options. The more important concern is the overall amount of financial incentive available to the ACO to invest in care coordination infrastructure and reduce utilization and costs. The current ACO incentives in Medicare are very weak.

D. Other approaches for increasing accountability

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

    - A model like this will only be a viable option in a small number of very tightly-knit communities with a strong sense of shared "medical destiny" among residents, private employers, physicians and other providers, and community groups. Grand Junction, CO and Rochester, NY have occasionally been identified as communities with these characteristics. There may be some others. In these settings, individuals and organizations must be willing to make choices that are sub-optimal from their own point of view in order to maximize the community good. Such communities will be relatively difficult to find, as there is no strong sense in the United States as there is in some other countries about public or community responsibility for health care or health outcomes. The failure of the Sustainable Growth Rate (SGR) approach to controlling physician expenditures at the national level is just one example of how individual-level incentives will trump a "community-level" initiative to manage cost or quality. There is some hope for management of cost and quality in an organizational structure to which providers and patients truly belong, and generally belong voluntarily. Aside from special circumstances like the examples cited, we see no hope for success for "community ACOs".

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More

specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

- Shortly after the passage of the Affordable Care Act, we proposed to CMMI a "mega-demonstration" that would bring together otherwise separate delivery concepts and demonstration project ideas. Primary care medical home, bundled payment for specific specialty care episodes, enhanced care coordination for care transitions, expanded use of electronic medical records and telemedicine were all part of the large concept proposal. This seemed a good idea at the time, and still seems a good idea, as many of the individual concepts can be expected to have synergistic effects when combined with others.

- One possible general "layered" model would have a Medicare Advantage plan at the "top" to take care of insurance functions, then one or more ACOs as contractors to the MA plan on some agreed-on payment model, including partial capitation. Hospitals and specialists would serve as contractors to the ACO, providing coordinated episodes of inpatient and specialty care on a bundled, episode payment basis. They would be selected by the ACO on a competitive basis using a blend of cost and quality metrics. Primary care medical homes could be either employed by the ACO and therefore be a distinct part of the ACO, or could be contractors to the ACO, again providing a defined set of services on an agreed-on payment model, with selection based on a mix of cost and quality metrics. Medicare beneficiaries joining the MA plan would also agree that their care would be provided by primary care medical homes and specialists and hospitals contractually linked to an ACO and the MA plan. Beneficiaries could have choices of ACOs within the MA plan, and primary care providers within the ACO.

- For hospitals and procedural specialists there are at least two closely related options for their success in an ACO environment. First, they could develop and be paid as a particular form of "specialty ACO". They could receive bundled episode payment for the kinds of acute, expensive episodes that they most naturally provide – surgical procedures, acute injury/trauma care, cancer diagnosis, staging, and treatment, and other well-defined episodes of secondary or tertiary care that fall outside the scope of primary care or regular chronic disease management. The ACO term, if qualified by some adjective like "specialty", could also be used, since payments for these providers could include formal accountability for both episode cost and quality (including outcome).

  In this "specialty ACO" model, hospitals and procedural specialists could be natural allies, as they seek to provide the highest quality and most efficient care for those patients and episodes of illness that come to their attention. The boundary between "general ACO" care and "specialty ACO" care would have to be managed carefully, but if the general ACO has incentives to avoid the need for specialty ACO care among its patients, then the specialty ACO may not have much opportunity to provide care and receive episode payment for questionable or preventable needs.

  In this "specialty ACO" model, there would be explicit organizational linking of hospital(s) and physicians, but only as a means to provide well-defined episodes of acute secondary or tertiary care. The episodes would start after the initial suspicion

of, or clear need for, acute care, and would end when patients are ready to return to more routine primary care or ongoing chronic disease care. In a region with more than one "specialty ACO", the ACOs may compete on the basis of cost and quality, with finite episodes of care as the basis for, and units of, such competition. In the absence of any formal affiliation with the "general ACO" in an area, a "specialty ACO" could compete with specialty ACOs in other regions to provide care for specific conditions, again, on the basis of both cost and quality. Their ability to receive patients efficiently from referring physicians or ACOs, their ability to manage acute episodes well and produce good outcomes, and their ability to return patients to the source of referral with well-developed follow-up plans would all be essential to success.

A related option is to become what has been termed a "focused factory" – an entity that does a small number of clinical things extremely well. In this case, the things to be done would be smaller than full acute care episodes. An imaging center, for example, may seek to become the provider of choice to several ACOs when imaging studies are needed. They may be paid by the ACOs through an agreed upon method. Likewise, an orthopedic surgery group and a hospital may come together to become a "focused factory" for joint replacement surgeries, and seek to become the provider of choice for those procedures, for the package of services involved from hospital admission to hospital discharge.

As the scope of "focused factory" services expands to look more like a full acute care episode, the conceptual line between a "focused factory" and a "specialty ACO" would blur to the point of invisibility, but there may be reasons related to licensure, liability, quality and cost measurement, or payment model that would justify keeping the models distinct.

The combination of bundled episode-of-illness payment and explicit pay for quality or pay for outcome component would fit either of these two models naturally. There are examples of this approach already in place, going at least as far back as some CMS demonstration projects on bundled payment approaches to cardiac surgery and more recently to "medical tourist" initiatives built on fixed prices and quality guarantees for defined service packages.

E. Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

   - Having the same patient attribution logic across all payers will facilitate adoption, from both other payers and ACOs.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

   - Agreement on a finite set of high-priority performance measures across payors is the key concept, and examples of this coordination of measurement already exist. There are examples of how full coordination cannot be achieved; measures of obstetrical or pediatric care, for example, are not important in Medicare but are important in Medicaid and in commercially insured populations. The key is to avoid conceptually similar measures that vary only in minor details for different payors

but would have to have separate data collection and analysis activities because of the minor differences.

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Dear Administrator Tavenner and Dr. Conway:

On behalf of the Healthcare Information and Management Systems Society (HIMSS), we are pleased to provide written comments to the Center for Medicare and Medicaid Innovation (CMMI), in response to its Request for Information on the Evolution of ACO Initiatives at CMS. We look forward to the opportunity for continuing dialogue with CMS as these payment delivery reform efforts evolve.

HIMSS is a cause-based, global enterprise producing health IT thought leadership, education, events, market research and media services around the world. Founded in 1961, HIMSS encompasses more than 58,000 individuals, of which more than two-thirds work in healthcare provider, governmental, and not-for-profit organizations across the globe, plus over 600 corporations and 250 not-for-profit partner organizations, that share this cause.

HIMSS' strategy for formulating this response to CMS began with convening a targeted workgroup of HIMSS members with expertise in payment and reimbursement issues, specifically how these issues relate to the health information technology arena. Since the RFI contained specific questions and discussion items that fell both within and out of HIMSS' scope, the workgroup identified relevant points to provide impactful feedback.

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

CMS Questions:

- *Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?*

- *If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?*
- *Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?*

HIMSS strongly supports the development and use of IT that will provide healthcare information required by emerging care delivery and business models and payment structures, such as Accountable Care Organizations (ACOs), to effectively manage and treat patients across the continuum of care including outpatient, inpatient, ancillary, emergency and post- acute care settings.[1] Anecdotal feedback suggests that the Pioneer ACO model has been modestly effective and cost-beneficial. Many throughout the health IT ecosystem can and will rely on the evolution of new business models fostered by pioneer ACOs and other delivery system reform efforts to refine the use of health IT to support improvements in care delivery.

Therefore, these evolving models play a key role in IT's evolution as well, by helping to encourage the adoption of interoperability standards and enhance design and usability of health IT tools in order to meet provider, patient and caregiver workflow needs. We believe that increasing opportunities for applicants for the next generation of Pioneer ACO models can help to further enhance the impact of the technology that underlies and enables these reforms. We support continued experimentation with payment models that will generate appropriate incentives and reward the most efficacious and cost-effective approach to treatment, given an individual's unique health and financial situation.

We encourage CMS to be open to the participation of a variety of care organizations, as the more diverse the organizations that participate, the greater the learning that will occur. For example, providers servicing different populations or similar populations with different geographic challenges may develop different strategies for meeting the same requirements. The greater the variety of approaches employed by program participants, the greater the possibility of identifying best practices for specific situations.

We note it is important to acknowledge the challenges inherent in the current population-based payment model that act as deterrents to participation.

- Many current and previous participants in the CMS Pioneer ACO Program have cited difficulties in tracking the progress and health status of patients who have the option of receiving care outside of the ACO without notifying the ACO.
    - In situations where the patient notifies the ACO they are planning to, or have received care outside of the ACO, the absence of a fully functioning health information exchange impedes the ACO provider's ability to maintain a comprehensive picture of the care the individual is receiving or to track the individual's progress or regression on specific measures.

[1] HIMSS 2013-2014 Public Policy Principles: http://himss.files.cms-plus.com/FileDownloads/HIMSS-Public-Policy-Principles-2013-2014.pdf

- Many health IT systems in place in a provider's office are still evolving; as a result, such settings currently lack the level of sophistication needed to track information at the level of detail required under the Pioneer ACO program.

With many variables outside their control, organizations find that the risk associated with accepting responsibility for patient outcomes outweighs the potential rewards. To address these concerns, CMS could consider implementing patient incentives that would encourage individuals to receive routine care within their assigned ACO, coordinate specialty care received outside the ACO with their ACO Primary Care Physician, and request that any practitioner who treats the individual provide a copy of the clinical records for that visit or episode of treatment to the individual's assigned ACO. For our part, the health IT community will continue to work toward interoperability that leads to the information exchange ACOs will need to be successful.

Population-Based Payments (PBP):

HIMSS offers observations on two CMS questions that are within scope of our expertise.

- *Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?*

Having a choice could enable the applicant to see benefits in concurrent programs—i.e., the EHR Incentive Program and payer-specific performance-based programs—to reduce risk of failure. We acknowledge that different markets support flexibility in payment models, and differentiating Part A and Part B Fee for Service (FFS) reduction amounts could allow flexibility in the technology deployed to achieve the Triple Aim of ACOs—reducing costs, improving patient experience, and improving health outcomes. An important consideration for some, however, will be whether or not the reduction amounts take into consideration the medical severity of the population being served. It is critical to the success of the program that those entities whose level of expertise or geographic location attracts a more acute case load are not adversely affected for becoming centers of excellence or meeting critical community needs.

- *Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?*

Actuarial capabilities of technology are becoming more sophisticated, allowing us to determine the financial risk and impact of specific patients and populations of patients. We caution that, by requiring specified levels of savings in prior years for eligibility, CMS might inadvertently encourage uses of technology to manage populations against an ACO specific internal benchmark, which could lead to detrimental impacts on specific patients. CMS could consider using aggregated data to develop a severity-adjusted benchmarking scale that links cost data to episodes, and allows ACOs to compare their populations to that scale.

- *Should any additional refinements be made to the current Pioneer ACO PBP policy?*

One way CMS could help ensure the success of these programs is to refine the current PBP policy to provide timely analytics and forecasting data. These forecast models and readjustments could be based on longitudinal data analytics that can project medical loss ratios on a routine basis. Technology is available for Medicare Shared Savings Program (MSSP) ACOs to utilize real-time eligibility information. For next generation ACOs to succeed, it is vital that the Pioneer ACO policy be modified to support real-time eligibility data and real-time identification of the beneficiaries who comprise the ACO panel, as well as much more timely delivery of claims data. This is necessary not only for proper functioning of the complex analytic models, but also for ACOs to guide and support their providers in utilizing the patient-centered, coordinated care that is the key to improving outcomes and lowering costs.

Our members' experiences with existing pioneer ACOs suggest that refinements may be needed on current minimal savings rates that must be demonstrated to be eligible for PBP. This mitigates some of the model adoption hesitation by potential applicants because of the significant investment in time, resources, and IT. Additionally, there is concern with the sustainability of the current CMS ACO model. There is opportunity for clinical workflow efficiency and quality outcomes improvement with the coordinated and proactive treatment of chronic conditions, particularly diabetes or heart disease, however concerns remain regarding what return on investment will look like.

There is also concern about potential downstream impacts for IT, should these savings not be demonstrated—cuts for staff, including IT, as a byproduct of these ramifications. We note that IT staff is critical for data generation for existing Pioneer ACOs. These ACOs with innovative and viable business models should research best practices in IT solutions that will be key to ACO success for demonstrating quality outcomes. These best practice technology solutions for this type of reporting will be instrumental to the success of ACOs, as well as mitigating the potential IT staffing loss risk associated with not meeting the targeted required savings objectives. Finally, larger healthcare institutions could find it difficult to identify which patients are to be managed under the ACO. This differentiation of status may cause a difference of care protocols for different populations at large institutions.

Section II: Evolution of the ACO Model

CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

Transition to greater insurance risk:

While the questions in this section do not fall neatly within the HIMSS scope, we offer the following observations on program issues specifically centered around two questions posed by CMS:

- *What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?*
- *What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?*

To ensure the greatest opportunity for success under a shared risk model, it is important that risk be appropriately distributed between the ACO and its payers, with ACOs bearing enough risk to encourage effective management of their population of patients without putting them in peril of being unable to maintain their business. We note it is also important that any risk model allow for the severity of an individual ACO's population and demographic or geographic attributes and that the ACO have appropriate financial reserves in place to protect it against the risk it is assuming. Finally, CMS should be thoughtful about state regulations regarding the assignment of risk between carriers and providers and work to ensure that any approach avoid being negatively impacted by state requirements.

CMS asks "*what are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?"*

Creating a locally-based trend analysis for ACOs to determine capitation rates could be beneficial, as well as a comparative analysis component between local and national benchmarks. It would also be beneficial to compare with HIE entities. HIMSS encourages CMS to utilize analytics to support progress of ACOs and promote effective and accurate coordination of benefits between payers, durable medical equipment (DME), and pharmacy marketing quality controls. These efforts can also aid in identifying fraud and abuse.

Finally, CMS asks *"what are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)"*

An effective strategy for risk adjustment should consider environmental, demographic and socio-economic factors affecting the population which a particular ACO serves, and a standardized approach allowing for the variances in population among different ACOs. One of the challenges with the current MSSP ACO risk-adjustment methodology is that it is perceived as preventing modifications to the individual patient Risk Adjustment Factor (RAF) scores as long as the patient is continuously assigned to the ACO. Replacing the RAF component of the current MSSP

ACO risk-adjustment methodology with a more flexible risk-adjustment strategy would create an environment where incentives for ACOs could be more effectively aligned with treatment protocols.

Integrating accountability for Medicare Part D Expenditures: In the RFI, CMS notes that an approach for "*increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.*" While not all of the questions in this section fall within the HIMSS scope, we offer the following observations on the following question raised by CMS on the topic of ACO data.

- *Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?*

In general, ACOs are not perceived to have timely data, or even the volume necessary to accept full risk for Part D expenditures. While CMS provides claims data, the challenge is that this data may not be timely or comprehensive enough for a risk determination—for this, clinical data is needed. More clarity is needed on what the risks are and what the potential to manage the risk is. Capturing both structured and unstructured data elements in clinical records should also be considered. Currently, there is no requirement of transmission or reception of prescription drug data between pharmacy and provider systems; if ACOs are to assume full risk for Part D expenditures, CMS should consider this point.

We recognize that many care coordination efforts utilize Part D spend as an offset to reduce other categories of spend, and as such, accepting risk for Part D requires that the ACO be fully functioning on all other spend categories, or aggregate spending could increase. Therefore, the use of technology to coordinate the beneficiaries' care across the continuum will require improved timeliness and completeness of the data for all categories of spend provided by CMS. An example will be real-time eligibility transactions in addition to Part A and B claims which must arrive much faster to support Part D risk-taking by the ACOs.

Integrating accountability for Medicaid Care Outcomes: As CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes, HIMSS offers the following observations on the questions posed.

- *CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?*

- *What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid*

beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

The technology and tools necessary to effectively manage Medicare populations are transferable to the Medicaid population, and therefore on a voluntary basis, many of the ACOs are preparing to assist with Medicaid populations. Without a Medicaid managed care model, many patients move in and out of Medicaid eligibility over the course of a year. As such, the care of these patients is frequently fragmented, distributed across multiple ambulatory and hospital records and with disparate medical record identifiers. This makes it challenging to incorporate and manage in an ACO care delivery model.

On the other hand, enrollment in a managed care plan requiring a primary care provider should result in better care coordination with less emergency department utilization. Administrative information available from such a setting might then be significantly more coherent, thereby encouraging the assumption of risk. An enrollment model without requirement for a care manager, while helpful, would likely be inadequate to assure the data coherence necessary to encourage risk assumption. Such managed Medicaid models exist (e.g., Louisiana) and appear to result in improved care at lower costs. This care management system should include clear incentives that motivate the beneficiary to accept the care and recommendations of his ACO provider team, which is key for the success of both Medicare and Medicaid ACO programs in the long term.

- *What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?*

Use existing IT capabilities where these capabilities are fully functioning. That being said, we acknowledge that these can be challenging to obtain. We also note that integrating information from ancillary care sources, such as clinics, nursing homes, etc. could be difficult as these systems are disparate and syncing the data could prove difficult. A data clearinghouse could be a viable option.

Multi-Payer ACOs: *CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.*

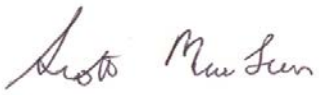
- *How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?*

The single most valuable contribution that CMS can offer in this area is to develop national uniform quality metrics, and apply them across the full continuum of care. CMS should continue its thought leadership on efforts to create uniform quality metrics and work with HIMSS and the

health IT community to facilitate efforts to establish a clearinghouse of quality measures for multi-payer ACO arrangements.

HIMSS appreciates the opportunity to comment on this RFI, and we look forward to offering our members' voices on IT issues, opportunities, and challenges surrounding payment delivery reform efforts. For more information, please contact Thomas M. Leary, Vice President of Government Relations, 703.562.8814 or Stephanie Jamison, Director of Government Services, 703.562.8844.

Sincerely,



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Health Sisters Health System
CMS ACO RFI Response
February 28, 2014

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Please select the option that best describes you.

- Part of a Medicare ACO
- **Part of a Commercial ACO**
- Part of both a Medicare ACO and a Commercial ACO
- Not part of a Medicare ACO or a Commercial ACO

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

Part A: Interest in Additional Pioneer ACOs

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model?
   Yes
   No

   A. Why or why not?

   Hospital Sisters Health System (HSHS) appreciates the opportunity to respond to the request for information (RFI) "Evolution of Accountable Care Organization Initiatives at CMS" as released by the Center for Medicare & Medicaid Innovation (CMMI) on December 20, 2013. In this letter, we offer feedback and recommendations to this RFI.

   HSHS is an integrated, multi-institutional healthcare system of 13 hospitals and numerous physician practices throughout Illinois and Wisconsin. We are committed to delivering high quality, compassionate, holistic and cost-effective healthcare services to all. HSHS is sponsored by the Hospital Sisters of St. Francis, an international congregation dedicated to carrying forward the healing mission of Christ in the tradition of St. Francis and St. Clare of Assisi. With revenues of over $2 billion, our work is carried out by 14,000 colleagues and distinguished by substantial community benefits, with a special emphasis on the poor and vulnerable.

   Effective care integration is essential for HSHS, CMMI, and CMS to reach our shared goals of improved population health, better patient experience, and reduced costs. HSHS is pursuing a multi-pronged Care Integration Strategy that serves as evidence of some of our past, current, and future efforts and investment to achieve these goals:

   - ***Integrating care.*** We are collaborating with independent physicians in rural and mid-sized communities to strengthen care integration and align performance. In addition, the multi-site HSHS Medical Group is an integrated part of our system, and we have established strong partnerships with other single specialty and multi-specialty physician groups.

- ***Pursuing value-based contracting through a Physician Clinical Integration Network (PCIN).*** *Over 700 independent physicians belong to PCIN, sponsored by HSHS to pursue care integration and value-based contracting.*

- ***Advancing the Patient-Centered Medical Home (PCMH)***. As part of our effort to improve care coordination capabilities, we implemented the PCMH model in three rural sites and at Prevea Health, our Wisconsin-based medical group partner. These sites have been certified by NCQA as level 3 PCMHs. We recently expanded this effort to a total of 15 sites, all of which are showing strong evidence of reduced hospitalizations, lower ED use, and more efficient drug utilization.

- ***Integrating Health Information Technology (HIT) and patient care.*** We are preparing to attest to Stage 2 of Meaningful Use, implementing clinical informatics capabilities system-wide and unifying healthcare delivery by using technology and professional relationships to link patients, providers, and care facilities.

In our comments below, we offer our experiences and provide our recommendations for evolving the Medicare Shared Savings Program (MSSP) and Pioneer ACO Model to ensure their sustainability and ability to improve the healthcare of Medicare beneficiaries.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?
   --Limit the number of selected organizations
   --Accept all organizations that meet the qualifying criteria

   A. What are the advantages and/or disadvantages of either approach?
      We recommend that CMS continue to allow organizations to become Pioneer ACOs. As providers develop the capabilities to take on more risk, they should have the opportunity to take on risk at higher levels if they are willing to. Given that providers are at various stages of developing the relevant capabilities, it would make the most sense to allow providers to apply to become a Pioneer ACO on an annual basis, similar to the timeline afforded to MSSP applicants.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?
   [BLANK]

Part B: Population-Based Payments for Pioneer ACOs

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP?
   Yes
   No

   A. Why or why not?
      Given that providers are continuing to learn best practices for managing financial risk, we recommend that CMS and CMMI allow for ongoing flexibility as ACOs gain the necessary capabilities. Since Part A and B services have different levels of unpredictability associated with spending, CMS and CMMI should phase in different FFS reduction amounts gradually. Although some providers have succeeded under the current Pioneer Model, others have not, including those who are otherwise thought of as high-performers. Since organizations

engaged in such models are not representative of all providers, it is vital that CMS and CMMI offer additional support and flexibility to other providers as they take on more risk and accountability for cost and quality of care.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?
   Yes
   No

   A. Why or why not?
      Even if added to the list of ACO participants, DME suppliers will have a low incentive to reduce spending because of the method by which they are primarily reimbursed. As a result, we believe that for DME suppliers to be effectively incorporated into an ACO they would need to be acquired by a provider participating in an ACO. Only then will their incentives align with the goals of the ACO.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves?
   Yes
   No

   A. Why or why not?
      HSHS recommends that CMS and CMMI outline clear requirements for financial reserves or require a Pioneer ACO to demonstrate that they have a reinsurance policy that would cover any near-term ACO losses.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?
   Yes
   No

   A. Why or why not?
      As with many of the issues included in the RFI, the concept of population-based payment represents an aspirational attempt to move healthcare networks toward overt insurance risk management. Several difficult considerations are involved in such a move:

      - First, it is unclear whether the minimum population thresholds required for Pioneer participation are of sufficient scale to provide a stable risk pool, especially if ACOs will be moving to full capitation and will lack the flexibilities afforded MA plans in managing such broad risk.

      - Second, insurance has long been a state-regulated industry, and it is unclear whether population-based payments infringe on a state's regulatory framework. As many ACOs operate across state lines, CMS and CMMI will need to ensure that ACOs are given appropriate federal guidance and flexibility.

      - Third, the persistent challenges with patient freedom of choice and spending targets need to be addressed before risk-based payment models can be implemented effectively.

The transition to population-based payment would require substantial re-thinking of insurance regulation, actuarial capabilities, and differential incentives for patients to remain in network.

SECTION II: Evolution of the ACO Model

Part A: Transition to Greater Insurance Risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations?
   Yes
   No

   A. What are the potential benefits and risks to the Medicare program and beneficiaries?
   ACOs take on a certain level of insurance risk by assuming aggregate spending responsibility for a specific population. Increasing the amount of insurance risk that ACOs assume, however, would dilute the effectiveness of the program unless other changes are made to the fundamental tenets of the ACO model:

   - By design, ACOs lack the ability to "lock in" beneficiaries to a preferred network of providers, and are unable to vary coinsurance and cost-sharing policies that would otherwise encourage care provided by ACO participants. In addition, many of the measures that provider performance is based on require beneficiary action—which is out of the control of the provider. Offering beneficiaries financial incentives could help facilitate more active engagement, improve quality, and reduce costs.

   - Offering capitation with insurance risk to ACOs increases the risk of loss, leading not only to potential failures to pay for care, but also the loss of assets of the ACO members and the discontinuance of healthcare services in the area as assets are liquidated to cover losses. Further, integrating additional populations—such as Medicaid individuals—into an ACO model with full insurance risk *without* a requirement that such ACOs establish sufficient capital reserves, or participate in a federally-facilitated reinsurance program, would likely result in an abandonment of the program by many ACOs while increasing the risk of loss for those who remain in the program.

   These two issues illustrate the major issues that we believe will arise if ACOs are required to take on full capitation, but are not given the same amount of flexibility as an MA plan. CMS and CMMI should ensure that, if ACOs are to be accountable for the full insurance risk of their attributed population, that there are mechanisms in place, similar to those available for MA plans, which the ACO can use to manage risk appropriately, such as differential cost-sharing for seeing a provider in-network versus out-of-network. In addition, ACOs should receive comprehensive, timely, and usable data from CMS on the beneficiaries attributed to them on a more frequent basis.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)
   As mentioned in our response to Section II – Part A – Question 1A, we believe that ACOs at full insurance risk can be responsible for Medicare Parts A, B, and D. However, ACOs will need to receive additional flexibility from CMS, CMMI, and states in how they are able to engage beneficiaries to manage costs.

In addition, we recommend delaying including Medicaid beneficiaries into the MSSP or Pioneer ACO Model for now. Integrating Medicaid enrollees into these models would present most ACOs with actuarial challenges that could prove insurmountable. It is projected that up to 20% of Medicaid enrollees will "churn" through the program annually, making actuarial predictions difficult for an ACO bearing full insurance risk.

3. Are there services that should be carved out of ACO capitation?
   Yes
   No

   A. Why or why not?
      We recommend that, in addition to excluding beneficiaries above the 99th percentile, CMS also exclude beneficiaries that have received transplants that year, those with ESRD, those, with Medicaid long-stay nursing home expenses, and those whose episodic costs exceed $100,000 in a year.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?
   For an ACO to take on full insurance risk, it will need access to providers outside the ACO. The ACO can obtain access through three means:

   - First, the ACO could contract with a national insurance company for access to its panel of Medicare Advantage providers, its negotiated reimbursement rates, and its medical management capabilities.

   - Second, the ACO could contract directly with an expanded panel of providers.

   - Third, the ACO could reimburse non-ACO providers at current Medicare FFS rates. This approach, however, would fail to address the issue of how to ensure that external providers comply with the ACOs care management processes and procedures.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk?
   HSHS recommends that CMS and CMMI:
   - Remove the 3-day inpatient stay requirement for Medicare-covered admission to a skilled nursing facility,
   - Continue risk-adjustments based on hierarchical condition category methodology,
   - Eliminate restrictions on treatments that physicians decide are necessary,
   - Verify that ACOs have proven financial assets in reserve,
   - Assess level of beneficiary access to ACO providers.

   A. What regulatory and compliance elements in Medicare Advantage would NOT be appropriate for ACOs assuming full insurance risk?
      [BLANK]

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities?
   Many states have capital reserve requirements for risk-bearing entities. However, given the limited capital available to ACOs, HSHS recommends that CMS and CMMI work with states to remove these requirements for those in MSSP, instead requiring ACOs to join a federally-facilitated ACO reinsurance program. In addition, CMS and CMMI should work with states to

remove the requirement that risk-bearing entities file with their states on an annual basis, especially in the initial years of the program given the potential for fluctuation in ACOs' formation.

A. What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?
[BLANK]

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?
For ACOs to expand to full insurance risk or for aspirant ACOs to be able to enter the field, they will need to build or buy insurance capabilities, such as claims processing, member services, sales and marketing, and public relations. Without adequate funding, such as the above-expected reimbursement levels that were offered to insurance companies to enter the Medicare Advantage market, ACOs will not be able to effectively manage financial risk. As mentioned in the response above, CMS and CMMI should consider developing a federally-facilitated ACO reinsurance program that is similar to the federally funded stop-loss program established under the Affordable Care Act to assist in the development of new ACOs, especially in underserved and rural areas.

8. The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are approaches for setting appropriate capitation rates?
[BLANK]

A. What are the advantages and disadvantages of using national expenditure growth trends?
[BLANK]

B. What about for using a local reference expenditure growth trend instead?
HSHS recommends that CMS use a blended expenditure growth rate trend that combines the local rate (likely at the metropolitan statistical area level) with the national rate. This will help to support the formation of ACOs in areas where spending is already below the national rate and would encourage ACOs in areas where the spending is above the national average to reduce spending growth more rapidly than if they were just being benchmarked against the local rate.

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)
Though the HCC methodology isn't ideal, it currently is the most appropriate methodology for adjusting risk that we are aware of. We would discourage CMS from using demographic risk adjustment since it does not apply well to the Medicare population given the reduced income of retirees and their poorer health status.

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes?
Please see response to Section II – Part A – Question 1A.

A. How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

Benefit enhancements should be differentiated not only based on whether they fall under Parts A, B, or Medicaid, but also whether the services are delivered in or out of network. Part D benefit enhancements should be based on use of generic alternatives.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?
    Please see response to Section II – Part A – Question 1A.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice?
    To increase beneficiary protections, CMS and CMMI should require ACOs to submit marketing materials for review and approval prior to distributing them. If an ACO uses unapproved materials, they should incur a financial penalty. In the most egregious of cases, CMS and CMMI should remove the ACO from the program. In addition, all sales agents or brokers employed or contracted with by the ACO should be licensed.

    A. What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?
       As long as beneficiaries have the freedom to seek care from any provider who accepts Medicare, then CMS and CMMI may not need to add protections to avoid adverse selection. However, CMS and CMMI should confirm through regular surveys that beneficiaries know they can see any provider.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology?
    Yes
    No

    A. What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?
       Since many providers are not yet affiliated with an ACO, voluntary alignment would create an institutional bias in favor of those organizations that pursued the model from the start. These early ACOs would have time to create and implement beneficiary engagement and marketing strategies designed to enroll the healthiest and lowest-cost individuals. This dynamic could lead to abuse and degrade freedom of choice as ACOs would only target the healthiest individuals, while higher-cost beneficiaries would be attributed to an ACO primarily through claims. For those reasons, we recommend that CMS and CMMI continue to attribute beneficiaries to ACOs based on the existing claims-based process. Only after a majority of beneficiaries—across markets—are in Pioneer or MSSP ACOs, should CMS and CMMI reevaluate the voluntary alignment option.

<u>Part B: Integrating Accountability for Medicare Part D Expenditures</u>

1. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?

HSHS is supportive of integrating accountability for Medicare Part D expenditures into the ACO program, though we do acknowledge some challenges.

- Most ACOs have limited experience in developing and managing outpatient formularies. In turn, formulary management would greatly benefit from an ACO's ability to vary cost-sharing requirements.

- The distinction between medical benefits and pharmacy benefits is an historic artifact that results in potentially significant misalignment between ACOs and Part D plans. It may be the case that Part D spending will have to increase as part of a concerted effort for medication adherence in order to reduce overall healthcare spending. Part D plans, however, have incentives to decrease overall drug spend. While most ACOs do not have broad experience with managing outpatient formularies, they will need assistance, but such assistance will have to be sought in ways that are unique to the Medicare program.

A. What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?
[BLANK]

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?
Yes
No

A. Why or why not?
Since ACOs, particularly fully capitated ACOs, must manage a broad scope of activities for their beneficiaries, we recommend that they look for opportunities to coordinate efforts with pharmacy benefits management companies rather than enter into direct, contractual relationships with them or assume full Part D responsibilities. For more information, please see the response to Section II – Part B – Question 1.

B. If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?
As mentioned in our response to Section II – Part A – Question 6, it is not feasible to have ACOs, in any manner, be licensed under state law as risk-bearing entities. Such a requirement would hinder the formation of ACOs by increasing administrative burdens for those ACOs that operate in multiple states.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures?
Yes
No

A. What other mechanisms would allow ACOs to assume accountability for Part D outcomes?
We also believe that ACOs will need to explore relationships with retail pharmacies directly if they are to be held at risk for Part D expenditures. There is greater alignment between ACOs and retail pharmacies, and pharmacies are more likely to be in a position to provide ACOs with the prescription claims and fill data in a timely enough manner to have effective adherence programs in place.

Part C: Integrating Accountability for Medicaid Care Outcomes

1. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?
Yes
No

   A. Why or why not?
   With state Medicaid and duals demonstrations already underway, we recommend that CMS and CMMI delay incorporating the Medicaid population into the federal ACO programs. Once these state demonstrations are further implemented and evaluated, the feasibility of combining these two disparate groups into a single program can be reexamined.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes?
[BLANK]

3. What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

   A. Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries?
   [BLANK]

   B. Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?
   [BLANK]

4. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?
[BLANK]

   A. What roles should States play in supporting model design and implementation?
   [BLANK]

   B. Do States have adequate resources to support an ACO initiative in collaboration with CMS?
   [BLANK]

5. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?
[BLANK]

   A. What are the capabilities of providers in integrating this data with electronic health records?
   [BLANK]

B. What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?
[BLANK]

6. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures?
[BLANK]

   A. Should CMS and States offer separate but coordinated shared savings arrangements to ACOs?
   [BLANK]

   B. Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?
   [BLANK]

Part D: Other Approaches for Increasing Accountability

1. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?
[BLANK]

   A. What are the most critical design features of a provider-led community ACO model and why?
   [BLANK]

   B. What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area?
   [BLANK]

   C. Are there models to consider that better integrate community-based services beyond the traditional medical system?
   [BLANK]

2. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?
Yes
No

   A. More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments?
   Yes
   No

   B. If so, what would the most critical features of such a “layered” ACO be and why?
   A layered ACO could be a valuable way to merge the best aspects of several payment and delivery reform models. However, CMS and CMMI would need a way to assess the efforts of each of the providers individually (e.g., aligning specialists under their bundle or episode and giving primary care providers separate per member per month payments). With separate quality metrics and financial models, the ACO convener would then need to consolidate the efforts under a single legal entity for CMS and CMMI.

Part E: Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?
   [BLANK]

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?
   [BLANK]

Johnson & Johnson

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VIA ELECTRONIC SUBMISSION

March 1, 2014

Patrick Conway, M.D.
Deputy Administrator for Innovation and Quality and CMS Chief Medical Officer
Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, MD 21244

RE: Request for Information: Evolution of ACO Initiatives at CMS

Dear Dr. Conway,

On behalf of Johnson & Johnson's Operating Companies (J&J), I am pleased to submit these comments and recommendations in response to the Request for Information (RFI) on the "Evolution of ACO Initiatives at CMS" released by the Center for Medicare and Medicaid Innovation (CMMI) on December 20, 2013.

J&J is the world's most comprehensive and broadly-based healthcare company, delivering products and services for the consumer, pharmaceutical and medical devices and diagnostics markets. For more than 127 years, J&J has led the way in innovation and is committed to creating scientifically sound, high quality products and services that prevent, treat, and cure disease and improve the quality of life for patients around the world.

J&J supports the healthcare transformation moving toward better care quality, better patient outcomes and lowering healthcare costs. Recognizing that no single participant or stakeholder group in the health care delivery system can accomplish this independently, J&J seeks to participate in the transformation through the creation of integrated care businesses and enabling solutions/technologies that support our products and put the patient at the center of healthcare. Examples of solutions include JANSSEN® CONNECT®, Care4Today Health Solution, and outcomes-based contracting strategies.

JANSSEN® CONNECT® helps patients start and continue on Janssen's long-acting injectable atypical antipsychotic treatment after a healthcare professional has decided it is the most appropriate clinical treatment option. The program addresses gaps in mental health treatment in the US by providing information and assistance to

patients. Specifically, JANSSEN® CONNECT® offers information and assistance by locating options for injection centers that may be more conveniently located for patients, information and assistance to help transition between care settings, research on coverage status, assistance coordinating medication shipment, and encouraging patients to follow-through with their health care provider (HCP)-directed treatment plan. Janssen Healthcare Innovation Care4Today Heart Health Solutions cardiac rehabilitation program is underway at the Henry Ford Hospital evaluating ways to improve health outcomes while lowering the cost of care. The program is testing ways to enhance the overall patient experience in cardiac rehabilitation by addressing the limiting factors of recruitment, retention and system inefficiencies.

J&J recognizes the potential that ACOs have to contribute to healthcare transformation and the Triple Aim. When matched with appropriate financial incentives and quality metrics, ACOs can encourage treatment options that are better tailored (based on available evidence) to individual patients' needs.

J&J seeks to work with ACOs and ACO participants to help them in their pursuit to quality and efficiency of care. This RFI provides a welcome opportunity for J&J to share some thoughts with CMMI/CMS based on our conversations with key customers, internal audience and trade associations. This letter includes four general recommendations corresponding with the RFI questions.

1. Enable flexibility to encourage innovative contracting arrangements;
2. Exclude certain breakthrough technologies (drugs, diagnostics and devices) from the ACO payment calculation to avoid disincentives to using breakthrough new technology;
3. Account for Part D drug costs in the calculation of incentive payments to prevent distorted prescribing behavior of shifting Part B patients to Part D; and
4. Advance quality measures to fill the gaps in clinical areas and ensuring cost savings do not negatively impact quality

Recommendation 1: Enable flexibility to encourage innovative contracting arrangements

This section focuses on *Section I (A). Population-based payment Question 1. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?*

Manufacturers, including J&J, are evaluating how they can provide new and existing product-related and other innovative health care solutions to these integrated providers in a manner that is aligned with healthcare reform objectives. These value solutions are designed to improve clinical outcomes at a lower cost. When ACOs see benefits of these value solutions, ACOs and manufacturers can enter different types of arrangements directly.

We want to emphasize that in an environment of pay-for-performance, ACOs and manufacturers should have greater clarity in innovative contracting arrangements that support these new value solutions. For example, manufacturers may bundle an array of products and consulting services to support an integrated system to improve patient outcome and efficiency in a hip/knee replacement surgery. In other cases, manufacturers and ACOs or ACO participants may enter into outcome-based contract where payment is based on percentage of patients that have achieved improvement in clinical outcome or quality of life. For patients who do not see clinical improvement, manufacturers may offer certain discounts or rebates to ACOs. ACOs and manufacturers may also enter into "shared savings" arrangements where both "share in the savings" generated through a manufacturer's offering.

However, several challenges exist around these types of arrangements. First, laws designed to protect against fraud and abuse in "traditional" health care delivery and payment systems, such as the Federal anti-kickback statute[1] and civil monetary penalties (CMP)[2] may dissuade manufacturers from pursuing certain contracting strategies. In particular, certain bundling strategies or outcome-based strategies may fall outside the current safe harbors under the Federal anti-kickback statute.[3]

Secondly, application of existing laws and regulations for Medicare Average Sales Price (ASP), Medicaid best price and other government pricing calculations can result in uncertain and potentially disproportionate negative impacts for certain types of contracting strategies. For example, manufacturers may be deterred by these laws and regulations from offering such potentially beneficial strategies as capitation or outcomes-based contracting strategies.

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[1] The Anti-Kickback Statute, 42 U.S.C. 1320a–7b(b)(1) and (2). Persons may not knowingly offer or receive, directly or indirectly, overtly or covertly, in cash or in kind, any remuneration to induce or influence the furnishing, arrangement, purchase, leasing, or ordering of items or services for which payment may be made in whole or in part under a federal health care program.

[2] 42 U.S. Code § 1320a–7a - Civil monetary penalties

[3] On November 19, 1999, the OIG published eight new safe harbor regulations to the Anti-Kickback Statute: (a) Investment Interests. (b) Space Rental. (c) Equipment rental. (d) Personal services and management contracts. (e) Sale of practice. (f) Referral services. (g) Warranties. (h) Discounts.

Lastly, when ACOs work with different stakeholders to improve patient outcome and efficiency of care, limitations on data sharing can challenge the ability to conduct real-time analysis. For example, the value of medication adherence programs may be difficult to assess for both ACOs and pharmaceutical companies without both having access to comprehensive data on patients' current medications and treatment plans.

These same barriers hinder multi-payer alignment of incentives to reduce cost and improve quality of care. To be specific, manufacturers may be dis-incentivized to enter performance-based risk sharing contracts with private payers for the reasons listed above even though these contracts may be cost-saving to the ACOs, patients and private payers.

J&J Recommends:

To enable flexibility in these types of innovative contracting arrangements, we encourage CMMI/CMS to consider permitting Federal anti-kickback statute waivers to Pioneer ACOs and their participants, and in limited and appropriate circumstances, to extend Federal anti-kickback statute waivers to manufacturers entering into innovative agreements with ACOs and their participants. We recommend CMMI/CMS work with stakeholders to explore this on a case-by-case basis.

We further recommend that CMMI/CMS engage with the OIG to evaluate possible flexibility/exemptions from the calculation of Medicare ASP, Medicaid Best Price, and other government pricing calculations for innovative solutions offered to ACOs by medical device or pharmaceutical manufacturers. There are a variety of risk-sharing arrangements that may benefit the objectives of ACOs in reducing costs while improving patient experience and outcomes. Often, such arrangements are not pursued due to the unknown or excessive financial risk these arrangements may generate under the government pricing rules. Consideration should be given to provide relief from pricing rules and other laws for these arrangements offered to ACOs for a sufficient period of time to allow experience with such arrangements to develop. After such time, a review of the pricing rules should be undertaken to assess whether changes are appropriate to those rules to incentivize contracting that aligns with the goals of ACOs.

Last but not least, improved ability to share data could help both ACOs and other stakeholders continuously improve care to patients. We applaud all the efforts made by CMMI/CMS already and encourage similar efforts going forward.

Recommendation 2: Exclude certain breakthrough technologies (drugs, diagnostics and devices) from the ACO payment calculation to avoid disincentives to using new technology.

This section covers topics in *Section I (A). Population-based payment Question 2. Should any additional refinements be made to the current Pioneer ACO PBP policy? & Section II (A). Transition to greater insurance risk Question 1. Are there services that should be carved out of ACO capitation? Why?*

As a leader in bringing innovative medical treatments and diagnostics to patients, J&J believes it is important to consider the potential financial disincentives ACOs may have to adopting new treatments which may not be reflected in their historical benchmark data. If ACOs are to be a successful alternative care delivery model, this issue must be taken into consideration. For example, Massachusetts' 2012 healthcare cost containment legislation protect patients' access to necessary health care services across the care continuum, including breakthrough technologies and treatments. [4] In addition, patients are given the right under the Massachusetts legislation to access new innovative treatments and medical services when not available within an ACO.

Because ACOs are rewarded for short-term cost savings, they face challenges with introducing breakthrough treatments where there are no offsetting costs during the benchmark period. For example, consider a potential new drug for Alzheimer's Disease. This devastating disease affects a large number of Medicare beneficiaries, with no existing therapy options (or only options of limited effectiveness), resulting in little or no spending for these patients in the baseline period. In this case, an ACO would be "penalized" for providing the new treatment to its patients as the expenditure for this new treatment will show up in performance years for a period of time and it may take more than one year to realize savings. ACOs might respond by limiting the number of patients to whom it offered the treatment or by avoiding patients having the underlying condition.

Moreover, to the extent that ACOs are paid on a capitated basis (i.e., population-based payment), innovative technologies may not be adequately included in capitated fees, as utilization of new technologies and novel medical breakthroughs is very difficult to predict on a facility level with enough granularity to ensure fair measurement. Consequently, ACOs are not effectively reimbursed to the extent their patients obtain these new technologies or treatment; even though these new technologies or treatment may have demonstrated a contribution to improvement in outcome measurement and/or have been demonstrated to product long term (greater than one, or even longer) cost offsets.

J&J Recommends:

To ensure that patients continue to have access to innovative medical technologies and ACOs are appropriately reimbursed, CMMI/CMS should create a process under which

[4] Chapter 224 of the Acts of 2012, Section 14(k)(c)(3), accessed at: https://malegislature.gov/Laws/SessionLaws/Acts/2012/Chapter224, on March 1, 2014.

stakeholders would be able to identify certain treatments (that is, those for conditions or patient populations for which treatments were previously unavailable or largely ineffective, and for which the costs of the breakthrough treatment would not be contained in the baseline "benchmark" data). CMMI/CMS should make an adjustment to remove incentives to underuse the new treatments. The adjustment could vary from case to case, but it generally would involve excluding certain Medicare expenditure data (across all settings) from an ACO's shared savings or shared loss calculations or excluding patients with the affected conditions from the ACO. When expenditures from the breakthrough treatment are reflected in the rate-of-increase factor (or in any subsequent benchmark years) then this adjustment would cease.

Recommendation 3: Account for Part D drug costs in the calculation of incentive payments to prevent distorted prescribing behavior of shifting B patients to D

This section focuses on *Section II (A). Transition to greater insurance risk Question 2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)* & *Section II (B). Integrating accountability for Medicare Part D expenditures 1. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?*

As fully explained in paragraphs below, to the extent ACOs have only partial responsibility for the costs of beneficiaries, they may have incentives to shift patient care towards those areas for which they are not responsible, such as Part D cost, private payers or Medicaid. Financial incentives that inappropriately influence the selection of treatment options is problematic, not only because of the access to quality care issues it may create, but also because it may cause patients to incur additional out-of-pocket costs, which in turn may impact adherence to treatment plans and ultimately, clinical outcomes.

Currently, Pioneer ACO's eligibility for incentive payments is determined by measuring savings under Parts A and B of Medicare. Although a substantial share of ACO enrollees are enrolled in Part D, drug expenditures under Part D are not included in determining the incentive payments. Hence, ACOs may have an incentive to shift Parts A or B expenditures to Part D. This incentive may be particularly strong in cases where Part D drugs may be seen as a potential alternative for drugs currently being furnished to patients under Part B. Such substitution would permit ACOs to reduce their measurement costs by writing prescriptions for Part D drugs in patients already well controlled and managed on a Part B agent.

We agree with CMMI that an approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery. Therefore, we support CMMI/CMS' efforts to incorporate Part D drug expenditures in the savings calculation for Pioneer ACOs, and we urge CMMI/CMS to expeditiously address the issue where it exists for other payment systems (e.g., the Medicare Shared-Savings Program [MSSP], episode care/bundled payment, and the Physician Value-Based Modifier). However, it is not clear at this point how many ACOs will be in a position to accept the risk of contracting as a Part D plan. According to the Evaluation Report of Pioneer ACOs, many Pioneer ACOs have not yet fully optimized their relationships with partners and providers, care management protocols, information management and IT systems, strategies for managing beneficiary leakage, or other core aspects of the ACO model.[5]

J&J Recommends:

[5] Effect of Pioneer ACOs on Medicare Spending in the First Year, by L&M Policy Research, Prepared under contract for CMS, November 3, 2013, page v, accessed at: http://innovation.cms.gov/Files/reports/PioneerACOEvalReport1.pdf, on March 1, 2014.

We recommend CMMI/CMS work with ACO participants to identify a pathway for ACOs to gradually take on risks for Part D expenditure.

First, and most importantly, CMMI/CMS should actively monitor ACOs to ensure that patients continue to receive the most appropriate therapy from these ACOs. Such monitoring could include a requirement that ACOs document the determination of the service, procedure, or item for their patients to demonstrate that a full array of technologies was evaluated. In addition, CMMI/CMS should establish an appeals process for patients and clarify how patient complaints will be arbitrated to ensure ACOs are not restricting patients' access to medically necessary care

In light of the potential for adverse selection in the Pioneer ACO program, particularly under a capitated fee arrangement, CMMI/CMS should consider instituting requirements aimed at preventing patient discrimination, similar to those by Medicare Advantage plans.[6]

In terms of a pathway for ACOs to gradually take on risks for Part D expenditure, we recommend that CMMI/CMS take an incremental approach before letting ACOs take on full risks of Part D. As a first step, CMMI/CMS should undertake an evaluation of current collaborations between ACOs and Part D plans, as it indicated it would do in recent Call Letters.[7] In addition, CMMI/CMS should engage stakeholders such as ACO participants and National Association of Insurance Commissioners to conduct analysis before allowing ACOs to accept insurance risk as Part D sponsors.

Until CMMI/CMS is able to include Part D drug costs in its evaluation of ACO's performance (and, where appropriate, other payment systems such as MSSP, the Physician Value-based Payment Modifier), we recommend that CMMI/CMS carve-out the costs of Part A or Part B drugs/biologics or procedures from the shared savings calculation where there is a Part D product substitute. This adjustment would help prevent payment incentives from distorting prescribing behavior. CMMI/CMS could accomplish this by analyzing its spending data for Part B and D drugs and biologics by diagnoses codes and common FDA label indications for the respective therapies, and removing the Part B drug costs from the expenditure data for both the benchmark years and the performance years when there is a Part D drug and biologics alternative. For procedures where extending medical management using Part D drugs may be an alternative to a procedure that would be paid under Medicare Parts A or B, CMS could similarly identify where these situations arise by analyzing its data and remove the costs

[6] For instance, ACOs would be prohibited from denying, limiting, or conditioning benefits to beneficiaries on the basis of factors such as medical condition, claims experience, medical history, and genetic information.

[7] For example, in CY 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, CMS expressed an interest in Part D Plan sponsors playing a greater role in managing the care of Medicare FFS beneficiaries and having greater accountability for overall health outcomes. CMS offers several principles for collaboration for Medicare ACOs and Part D sponsors considering forming such business arrangements.

of the procedure from the benchmark years and the performance years. J&J would be glad to provide technical expertise to CMMI/CMS for this analysis.

Once Part D becomes part of ACOs' expenditure and savings calculation, beneficiary protections need to be secured. CMMI/CMS should protect patients' access to appropriate therapies through minimum formulary requirements and ensure patients' out-of-network access to appropriate therapies. CMMI/CMS should include the statutory formulary review and transparency requirements included in Section 423.124 of the Part D statute. Protections must be in place for those who want to receive primary care in a Pioneer ACO, but may need to obtain some portion of their therapies outside of it (e.g., based on where they live or work or based upon the availability of appropriate specialists). To ensure these patients are able to retain this option, CMMI should hold Pioneer ACOs to the same standards as Part D sponsors in providing out-of-network pharmacy access to covered drugs without excessive cost-sharing [42 CFR § 423.124].

In addition, we want to emphasize the importance of protecting the robust private competition that has kept the Part D program working well to generate lower costs for seniors, while providing broader choice for enrollees. Therefore, we strongly urge CMMI/CMS to continue to rely on the current Part D bidding process, instead of creating a unified expenditure target, as it represents a successful market-oriented approach to ensuring timely patient access to innovative therapies.

Recommendation 4: Advance quality measures to fill the gaps in clinical areas and ensuring cost savings do not negatively impact quality

ACOs have the potential to improve patient care coordination, improve quality and reduce costs. Achieving this potential, however, requires balancing cost reductions with quality assurances. To ensure beneficiaries receive high quality care and enjoy a positive experience under the Pioneer ACO Model, CMS has established quality measures that have been used to monitor the quality of care provided and beneficiary satisfaction. CMS adopts the 33 measures used for Pioneer ACO Model from those in the MSSP. Specifically, these measures focus on four domains:

- Patient/caregiver experience
- Care coordination/patient safety
- Preventive health
- At-risk population
  - Diabetes
  - Hypertension
  - Ischemic Vascular Disease
  - Heart Failure
  - Coronary Artery Disease

While the existing 33 measures are quite detailed for those diseases and conditions identified in the at-risk populations listed above, many other diseases and conditions are not reflected in the list of measures. It is important to ensure that the cost savings incentive of ACOs does not negatively impact the quality of care for patients with any diseases, and that CMS have meaningful ways to monitor quality for all ACO patients.

The long-term success of the shared savings programs require that all stakeholders (e.g., patients, providers, and CMS) have confidence that any savings from the program do not come at the expense of quality patient care. CMS acknowledged in the MSSP Final Rule that "we would expect to refine and expand the ACO quality measures in the future and expand measure reporting mechanisms to include those that are directly based. Specifically, we expect to expand the measures to include other highly prevalent conditions and areas of interest, such as frailty, mental health, substance abuse, including alcohol screening."[8]

To be specific, CMMI/CMS should "advance" quality measures to align with priorities in the National Quality Strategy and include more measures on outcomes, patient engagement, patient experience, safety and reduction in potentially avoidable complications. Currently, few of the 33 quality measures are outcome measures (as opposed to process measures). Going forward, with more access to claims data and clinically enriched quality data, Pioneer ACOs will be better positioned to report outcomes measures. As CMS recognized in the Final Rule of Medicare Shared Savings Program, "it is important to start with a combination of both process and outcomes

[8] Page 67873, Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations Final Rule, November 2, 2011.

measures, but may move to more outcomes-based measures and fewer process measures over time."

Policy experts and measure developers also recognized that the measure set could be enhanced with other patient-reported outcomes measures in the areas of depression remission, functional status, smoking, and medically complex patients (e.g., chronically ill or those with multiple chronic conditions), as well as a measure of health risks with follow-up interventions.[9] We applaud CMS for including patient experience of care measures in the final list of 33 quality measures.

We would also note a three-year agreement period is potentially too short to allow accurate outcomes assessment for some diagnoses and treatments.

J&J Recommends:

We recommend that an ACO should describe how it was (or will be) able to ensure that quality is not negatively impacted as a result of the changes it made to generate savings in areas such as medication management, clinical improvement and efficiency improvement. In particular, it would be very important for CMMI/CMS to understand how quality metrics are applied, including the resulting data collected for those metrics.

In addition, we recommend that CMMI/CMS work with Measure Application Partnership (MAP) and other stakeholders to advance quality measures for Pioneer ACOs and MSSP. On December 1, 2013 MAP received from HHS a list of 234 measures under consideration for use in 20 federal programs. In the Pre-rulemaking Report, related to MSSPs, MAP recommended the addition of acute and post-acute care measures, measures relevant to patients with multiple chronic conditions and movement towards more outcome measures. These outcome measures are also important to balance the cost and quality issues around preventing incentives to shift patients from a Part B drug to a Part D drug, and encouraging physicians to stay focused on improving patient outcome. MAP reviewed 15 measures under consideration and supported the inclusion of five measures (as shown in the table below).

We recommend that CMMI/CMS work with the MAP and Pioneer ACO participants to pilot-test measure sets in areas where there are gaps, especially in patient-reported outcomes measures. It is also important to measure and monitor the extent to which patients are able to remain healthy and out of a doctor's office and hospitals, and thus, avoiding unnecessary health care services.

Measure Name	**MAP Recommendation**
NQF #0576 Follow-up after Hospitalization for Mental Illness	Support
Five measures that are collected through the Clinician-Group CAHPS (CG-CAHPS) survey: Courteous & Helpful Office Staff,	Support

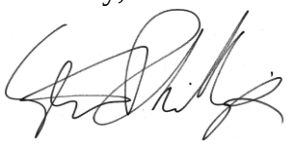
[9] Measure Applications Partnership Pre-Rulemaking Report: Public Comment Draft, January 2014

Supplemental Item Care Coordination, Between Visit Communication, Educating Patient about Medication Adherence, and Supplemental Item Stewardship of Patient Resources.	
CAHPS Survey, Patient Experience with Surgical Care Based on the Surgical Care Survey CAHPS (S-CAHPS).	Support
Optimal Asthma Care–Control Component	Conditional, needs more testing
SF-36 and Patient Activation Measure—patient reported outcomes measures (PROMS)	Conditional, needs more testing

CMMI/CMS could also consider including quality measures intended for the Physician Value-Based Modifier Program as part of the Medicare Shared Savings Program. These measures are increasingly focused on "outcomes" quality measurement that is so important in these new models.

We greatly appreciate the opportunity and the past collaborations with CMS to support the development and testing of innovative health care payment and service delivery models. I would be happy to discuss our comments or other topics in greater detail, and I can be reached at 202/841-3116, or sphilli7@its.jnj.com.

Sincerely,



Steve Phillips
Senior Director, Health Policy & Reimbursement
Johnson & Johnson
Worldwide Government Affairs & Policy

Kaiser Permanente Responses - Submitted on 2/28/14 at CMMI website

SECTION I

[The introduction below was submitted under Section I Q. 2 due to space constraints]

The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in the United States, delivering health care to approximately 9.1 million members in eight states and the District of Columbia and comprising Kaiser Foundation Health Plan, Inc., the nation's largest nonprofit health plan; the nonprofit Kaiser Foundation Hospitals which operates 38 hospitals and over 600 other clinical facilities; and the Permanente Medical Groups, independent physician group practices that meet the health needs of our members. Kaiser Permanente is committed to delivering high quality health care through cooperation and collaboration among providers, hospitals, our health plans, and our purchasers. We believe that greater clinical integration and shared accountability for quality and value will benefit consumers, the Medicare program, and will improve the U.S. health care system.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Yes No

1A. Why or why not?

Even organizations well-situated to participate, such as financially stable physician groups with strong leadership and a history of integrated practice, have struggled to meet performance standards and savings targets set for the Pioneer program. We believe that these difficulties have discouraged less experienced organizations from participating in the program**.**

[Due to space limitations of survey the paragraph below was moved to Section I 3]
Kaiser Permanente supports the robust criteria established for Pioneer program eligibility, but we remain concerned Pioneer program performance standards, thresholds, and timelines were overly ambitious. While there are many high performing medical groups and health systems, few have experience with performance-based contracts that include downside risk (See http://content.healthaffairs.org/content/31/9/1984.full?sid=a58eb7fb-b6ce-4b7b-a8be-ab8e53ca8c0e

An initial, limited set of quality and savings standards that could be expanded over time would achieve the right balance between attracting a larger group of organizations and improving their performance. Longer performance periods (e.g., 5 years) might ensure that early losses do not penalize Pioneers that are otherwise improving care delivery transformation and quality metrics. CMS oversight and collaboration serve both Pioneer ACOs and their beneficiaries (and the "learning networks" to which many ACOs belong). The close collaboration and oversight also provide some protection for beneficiaries.

Pioneers that achieve higher performance thresholds could be given greater opportunity for shared savings, population-based payments, and/or bonus payments (similar to the financial rewards associated with the Medicare Advantage "5 Star" demonstration and the bonuses described for "alternative payment models" in the evolving bipartisan SGR reform legislation currently).

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?

Kaiser Permanente supports the Pioneer program as an opportunity for organizations that want to improve their capacity for population-based care, to achieve "the triple aim," and implement alternative payment models. CMS should consider market conditions and the current geographic distribution of ACOs in deciding how to expand the program.

For instance, because Medicare Advantage is a better mechanism for integrated and accountable care, ACOs should be limited where Medicare Advantage market penetration is increasing steadily.

2A. What are the advantages and/or disadvantages of either approach? *See above*

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP?

1A. Why or why not?

As ACOs transition to population-based payment (PBP), flexibility in designing payment schemes will help ACOs finance care coordination and other care delivery improvements, and help them develop the appropriate mix of providers.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?

Yes, if the DME vendor is formally part of the ACO and beneficiaries are informed.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves?

3A. Why or why not?

Even well managed and integrated entities may not be able to hit their cost or savings targets every year. Thus it makes sense to evaluate ACOs by their progress developing systems to improve care and manage reources. ACOs should have flexible options but it is also critical that both CMS and the ACO fully understand the assumption of risks and work jointly to meet state solvency rules that apply.

SECTION II: Evolution of the ACO Model (to full risk)

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? Yes

1A. What are the potential benefits and risks to the Medicare program and beneficiaries?

Kaiser Permanente urges CMS to establish terms and rules that promote a **"**level playing field" (neutrality) between ACOs and MAOs. Under the Affordable Care Act, most MA benchmarks will achieve or approach "parity" with Medicare fee-for-service (FFS) per capita costs.

CMS should evaluate ACOs relative to both FFS and MAO costs and outcomes, and minimize incentives to shift beneficiaries between ACOs, MAOs, and FFS, depending on health status or payment "arbitrage" opportunities. ACOs and MAOs should have the same risk adjustment model. Beneficiaries are not required to get their care from their assigned ACO, which means ACOs assume significant risk for costs incurred externally—making capitation of ACOs riskier for the Medicare program.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

ACOs at full insurance risk should provide or arrange for Parts A, B, and D services, either in partnership with other organizations (e.g., Part D sponsors, health insurers) and/or through subcontracts with different providers.

3. Are there services that should be carved out of ACO capitation?

No. ACOs without internal expertise or specialized services to cover the full Medicare benefits package should have to identify and arrange for those services. ACOs unprepared to assume that responsibility should consider alternatives like bundled payment.

Why?

An ACO that bears responsibility for the full continuum of care will better manage coordination and transitions of care through efficiencies like interoperable health IT, shared clinical resources and systematic quality improvement programs.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

ACOs may want to include performance based standards in contracts they enter into with non-ACO providers.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk?

We recommend that states treat ACOs as risk-bearing entities; ACOs should also be subject to the Medicare MAO rules related to marketing and other beneficiary and program protections (network adequacy, grievance and appeals, etc). Flexibility can be provided in certain circumstances, for example, when a state payer may be helping to "backstop" an ACO.

What regulatory and compliance elements in Medicare Advantage would NOT be appropriate for ACOs assuming full insurance risk?

ACOs that assume full insurance risk should not be subject to anti-kickback rules.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities?

ACOs could find it challenging to meet reserve requirements and accurately forecast expected costs. CMS may need to serve as a "backstop" for ACOs, to a level of losses for a short period of time. Over time, the Medicare program should recoup losses from ACOs so that ultimately the program is held harmless.

What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

See above.

Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services.

7. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

ACOs will need actuarial and data analytic capability, as well as financial reserves and other financial and administrative infrastructure for paying claims. ACOs will need to establish operational support to ensure convenient and appropriate access to the ACO and its care delivery system.

The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking.

8. What are approaches for setting appropriate capitation rates?

Capitation rates should reference local Medicare FFS spending, as the MA does. Some adjustment may be reasonable for ACOs serving beneficiaries from larger geographic areas or those with low population density.

8A. What are the advantages and disadvantages of using national expenditure growth trends?

A national expenditure trend can capture components of costs (like drugs or IT) that are determined in national markets. Similarly, physician and executive recruitment also rely on national labor markets. Using a national trend rewards geographic markets that have been efficient and experienced lower local cost trends. Using national expenditure growth trends would also help achieve the goal of payment neutrality with the MA program.

8B. What about for using a local reference expenditure growth trend instead?

See above.

9. What are the advantages or disadvantages of different strategies for risk-adjustment?

We recommend using a single risk adjustment methodology across the MA and ACO programs to promote simplicity and payment neutrality across Medicare.

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes?

Experience from the MA program should inform these decisions. ACOs that meet certain MA standards could have the flexibility to provide "extra benefits" not currently covered by Parts A or B, and also be able to vary beneficiary cost-sharing (*See the MedPAC discussion at its Nov 2013 meeting*
http://www.medpac.gov/transcripts/aconov2013handout.pdf)

10A. How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

Anti-kickback issues could arise. Preventive safeguards might include a review and pre-clearance arrangement with OIG for certain arrangements.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice?

An open enrollment period and affirmative choice in the MA program helps protect beneficiaries from marketing abuses. CMS could incorporate similar mechanisms (aligned with MA Open Enrollment Periods) in the ACO program if ACOs are permitted to recruit beneficiaries who are currently enrolled in MA or aligned with another ACO.

What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

CMS should consider regularly monitoring ACOs to ensure they are not dis-enrolling sicker beneficiaries. *See previous responses*.

Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries.

13. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology?

If ACOs are permitted to compete for each other's beneficiaries (and with MA), an open enrollment period and one-year "lock in" commitment (similar to MA) would be reasonable and necessary.

13A. What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

Voluntary prospective alignment could minimize "leakage" of care provided outside the ACO and allow the ACO to take on full risk.

Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes.

1. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?

We do not support allowing ACOs to accept insurance risk for Part D. To be successful, Part D sponsors need significant size and scale. Risk corridors were created for Part D sponsors to mitigate the volatility and forecast risk associated with new therapies; ACOs are currently free under the rules to partner with Part D sponsors. These partnerships should be disclosed to beneficiaries.

1A. What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?

2A. Why or why not?

2B. If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

We do not see a rationale for creating a unified expenditure target and unified risk adjustment method, given the well-established MA-PD and stand-alone Part D programs with their respective risk adjustment mechanisms and bidding processes. We would support testing and evaluating this approach on a limited basis-- for example, in a specific geographic market where a Part D sponsor and ACO are interested in this kind of contracting with CMMI.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures?

3A. What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

Through the State Innovations Model (SIM) grants, CMS is working with states to design and test payment reforms to address health priorities identified by states and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations.

1. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

1A. Why or why not?

In general, KP supports efforts to integrate care for dually-eligible beneficiaries and streamline the rules for serving this population. The ACA established the Medicare-Medicaid Coordination Office within CMS; the Office is working with states and health plans on "three way" contracting demonstrations. We believe the tools and authority granted to this Office by the ACA would allow ACOs to be incorporated into those demonstrations.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes?

States may wish to foster integration across safety net providers, or rural providers, or perhaps build ACO-like arrangements that include academic medical centers. States and CMS may want to tailor payment reforms that accommodate these providers and populations. These kinds of collaborations should set clear goals, and select/design quality and performance metrics to enable evaluation and comparison of these demonstrations with the performance of different provider and delivery systems serving similar populations.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?

See response above

3A. What roles should States play in supporting model design and implementation?

States often know their markets well and have an interest in promoting competition and ensuring access to underserved populations.

3B. Do States have adequate resources to support an ACO initiative in collaboration with CMS?

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?

In general, IT vendors and other entrepreneurial organizations are attempting to assist providers in integrating data from multiple sources.

4A. What are the capabilities of providers in integrating this data with electronic health records?

4B. What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures?

(Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?)

Medicaid programs differ across states—in managed care experience; in historic payment rates relative to Medicare; in spending baselines; and in the mix of community and institutional services they support. Separated or unified shared savings arrangements must reflect these differences. Expecting immediate and significant savings may be unrealistic, particularly if plans and delivery systems are not given greater flexibility in delivering services and benefits.

1. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?

1A. What are the most critical design features of a provider-led community ACO model and why?

It would not be appropriate to subcapitate smaller, specialized providers.

1B. What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area?

1C. Are there models to consider that better integrate community-based services beyond the traditional medical system?

In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives.

2. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?

2A. More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments?

2B. If so, what would the most critical features of such a "layered" ACO be and why?

An ACO should be free to design payments within its delivery system, perhaps with reference to models, groupers, risk adjustment methodologies, etc. that CMS/CMMI is helping to design and support.

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

Innovative contracting arrangements are occurring between private payers and ACOs or ACO-like provider systems. The results are difficult to assess; it is still too early to draw conclusions about the durability of these arrangements and their impact over time. A core set of standardized quality and measures that yield publicly reported scores could allow ongoing evaluation, encourage accountability, and inform consumer choice.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

See response above

Center for Medicare and Medicaid Innovation
Request for Information: Evolution of ACO Initiatives at CMS

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Section II: Evolution of the ACO Model

A. Transition to greater insurance risk – ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice.

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

   CMS should offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations. CMS should support increasing risk in the Pioneer and MSSP programs, as well as in other programs, including Medicare Advantage. By shepherding providers along the risk continuum, CMS can help support providers drive value and outcomes-based health care decisions in a population management setting. The potential benefits include a faster transition from fee-for-service to full risk, as well as substantial evidence from Medicare Advantage that the Triple Aim objectives are achievable. Possible challenges include the mandated open-access and related attribution issues associated with the ACO model, as well as increased member and provider confusion on what programs are offered in the market and the ability of beneficiaries to decline that CMS share their claims data.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

   Given the successes achieved through the Medicare Advantage program, ACOs at full risk should be responsible for the same categories of spending as MA programs – Medicare Parts A and B. With Medicare Advantage plans generally being required to offer at least one plan that covers Part D benefits and with 83% of MA plans doing so, ACOs at full risk should also be responsible for Medicare Part D spending.

3. Are there services that should be carved out of ACO capitation? Why?

   No services should be carved out of ACO capitation. Like MA programs, ACO capitation should include Parts A, B, and D. In terms of specific services outside of CMS-defined services, such as dental and vision benefits, these should be optionally offered on a market-based value-add basis by the ACO, like some innovative MA plans currently do.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

   Full-risk ACOs will need to establish agreements with non-ACO providers that set cost and quality benchmarks aligned with those established for the ACO providers. These agreements should contract the non-ACO providers throughout the continuum of care and include value-based reimbursement based on population management techniques and supporting tools. With hospitals and outpatient facilities, contracts should maintain a model that favors primary care physician management of beneficiary care. Other aspects of these agreements could include information-sharing, transparency, and incentives.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would not be appropriate for ACOs assuming full insurance risk?

   All full insurance Medicare-related CMS programs should consist of the same regulatory and compliance elements so that there is consistency as the country moves through health delivery system transformation and payment reform. Potential exceptions to this are those aspects that are impacted by access and attribution differences between the ACO and Medicare Advantage programs. As industry changes develop, reforms to a portion of regulatory and compliance elements will likely occur as we learn more over time.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

   State licensure laws could create challenges if the risk arrangement were viewed as the "business of insurance". In such a scenario, ACO participants could be held to certain solvency standards that would be a barrier to accepting risk. In addition, in order to permit risk-sharing arrangements in ACOs, waivers to both federal and state fraud and abuse laws, as well as Stark laws, would likely be necessary; similar to what is currently available within the MA framework. ACO participants need to be assured that their arrangements do not have unintended legal consequences in the transition to value based care.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have, such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

   In addition to member/beneficiary services, which includes issue resolution, beneficiary satisfaction, and appeals processes, among other things, ACOs will need to develop quality management, cost and utilization management, and regulatory and compliance oversight.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about using a local reference expenditure growth trend instead?

    Capitation rates must fully incorporate both spending trends based on the historical data and savings thresholds calculated for a specific assigned population to ensure a high level of confidence that overall success can be achieved. National expenditure growth trends can be significantly different than local expenditure growth trends and may deter entities from entering ACOs; therefore, local expenditure growth trends should be used to set appropriate capitation rates. It is important that while regional growth trends are acknowledged, the true test of achievement under capitation is to understand one population and target improvement for those beneficiaries.

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

    Medicare Advantage risk adjustment methodologies adequately compensate for the acuity of the patient.

10. What benefit enhancements would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

    Full-risk ACOs could offer benefit enhancements such as relief around deductibles & coinsurance should a non-copay structure as currently exists in traditional fee-for-service be maintained. On the other hand, should a copay structure be adopted instead of Parts C and D, reduced co-pays for services delivered by ACO providers could be offered as a benefit enhancement. Overall, incentives to participate in health and wellness programs could be offered as well. If full-risk ACOs were to become responsible for Medicare Part D spending, medication adherence and/or medication therapy management programs could also be offered.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

    The mandated open-access to providers and related attribution issues associated with the ACO model is one of the greatest challenges to moving to a full insurance risk model, along with the ability of beneficiaries to decline that CMS share their claims data.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What

are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

Potential marketing abuses could come from ACO providers attempting to eliminate high risk individuals or to attract low risk individuals through the use of scare tactics or misleading behavior. A possible solution would be to impose similar marketing restrictions on an ACO's materials and actions as are imposed upon Medicare Advantage brokers and plans. The challenge that arises with this is that much of the provider-beneficiary communication will be face-to-face, as the patient already has a relationship with the provider participating in the ACO. Face-to-face communications receive significantly less oversight as they are not considered "marketing" in the typical sense. This may require that CMS take action to ensure that beneficiaries understand that they have freedom of choice and that if their provider indicates otherwise, they should report this to CMS. CMS will have to assume a larger role given that what happens behind a closed provider's door is harder to regulate than a MA health plan sending marketing materials out to the public. It may also be possible to monitor the movement of beneficiaries between providers and ACOs to see if patterns emerge that indicate providers are inappropriately prompting movement in some way.

To avoid adverse selection in a full-risk ACO, we recommend that the policy and associated processes be altered so that an ACO-participating primary care physician, who is designated by the beneficiary as his/her PCP, receives immediate ACO attribution. Additionally, requesting all Medicare patients to designate a PCP upon enrollment and allowing that designation to be updated at any time at the discretion of the beneficiary could help address multiple challenges, including adverse selection, choice limitation, and attribution-driven risk management. Claims-based attribution could then be used for beneficiaries who do not designate a PCP. Furthermore, requiring (vs. just requesting) a PCP designation could eliminate current retrospective attribution challenges.

Finally, in order for an ACO to not use panel size for adverse selection, the ACO must be able to accommodate the wishes of the beneficiary through medical home and team-based care approaches to account for a wide range of panel sizes. To reduce PCP-changing variances, attribution could be designated for only the time period a beneficiary is associated with each PCP. This would likely require an analysis by CMS to understand the impact on quality measures, risk reserves, and other nuances that may result from this type of mid-year change.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

The advantage to allowing beneficiaries to voluntarily align themselves to an ACO, or preferably a PCP, is better accuracy than reliance on claims-based attribution. Patients are more likely to engage in their care when they select a PCP and develop an ongoing accountable partnership with them.

Center for Medicare and Medicaid Innovation
Request for Information: Evolution of ACO Initiatives at CMS

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes based contracting. The Model is now entering its third performance year with 23 organizations. In addition to increasingly aggressive risk arrangements, CMS offers eligible Pioneer ACOs the opportunity to transition from fee-for-service payments to monthly population-based payments to give these organizations more revenue flexibility in determining how to best motivate providers to improve quality of care and reduce costs for their patient populations. As more and more health care organizations begin to hone their skills in care coordination and engage in outcomes-based contracting, CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

Provider Organizations who have had experience with risk based contracts and success at managing these contracts may be interested in applying to the Pioneer ACO model in upcoming years. However, this assumes that the volatility of the financial model including problems with the benchmark methodology is addressed by CMS. This will also need to be addressed to maintain the current ACOs level of participation in the program.

The quality component of the ACO program is also a barrier. The current measure sets lack validity in improving health outcomes and the benchmarks should be re-evaluated. The process for capturing these measures is cumbersome; it requires data extraction from multiple EMR systems that not all organizations can easily access and extensive hands-on chart reviews done by clinical staff.

In risk arrangements with health plans we have the ability to use the claims data set we receive to be able to have a comprehensive understanding of the budget setting process and the ability to tie out expenses to ensure that our settlements are being calculated correctly. This data also allows us to more accurately identify patients that require additional care management services. We understand there is a limitation due to the data "opt-out" offered to beneficiaries, however, this causes a barrier for us having a comfort level that our reporting and settlements are accurate and leaves us unable to capture a comprehensive picture of our population to be managed. Part of our care team includes a team of Licensed Social Workers; the lack of behavioral health data in our claims data set limits us on incorporating these services into our care management model through use of data. These will continue to be barriers for both existing and new ACOs unless data limitations are addressed.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

We believe that CMS should accept Pioneer applicants that meet the qualifying criteria. Additional ACOs may lead to more uniform patient care for Medicare Beneficiaries and uniform expectations for physicians regardless of which organization they belong to. We don't believe there would be any disadvantages in this approach. If additional ACOs are added to the program, CMMI will need to be mindful of having appropriate staffing levels to assist ACOs. Staff turnover, which is understandable, has led us to experience a level of frustration with having our concerns and questions addressed timely. Our expectation would be that a larger ACO network would not further dilute the servicing model currently in place.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

Budget Considerations:

Pioneer ACOs have invested a large amount of infrastructure dollars in ACO development before seeing a return on this investment. There are ways CMS could help fund this investment. Some additional refinements could be exploring a way to modify cash flow to allow for infrastructure dollars to be paid to ACOs (e.g., investments or pre-payments on surplus dollars throughout the year), or by providing infrastructure payments to ACOs that have demonstrated savings under the Pioneer model.

In order to sustain those currently participating and attract additional ACOs there needs to be a stable and secure benchmark approach. Benchmarks and baseline expenditures should reflect regional/local averages, this would help alleviate budgets for low cost providers and offer a fair comparison to determine surplus. CMS should take lessons learned from the past 2 years and build that into any new methodology developed.

We recommend that CMS come up with a less complicated financial model; this will help with continued engagement from current ACOs and may attract additional ACOs. Under the current model we may understand the methodology at a high level, but are used to being experts on the granular details with other health plan contracts. The current model does not allow for that due to the complexities. We appreciate the webinars made available to assist with understanding the methodologies, but unfortunately many ACOs are still left feeling uncomfortable with the methodologies in place.

Surplus Sharing & Quality Scores:

We would suggest exploring changes to surplus sharing adjustments made based on quality scores. There should be a reasonable size band on performance before a quality score would lower surplus sharing (e.g., 80-100% score = 100% of surplus share; 70-80% score=90% surplus share). Furthermore, for organizations to want to continue to participate in this model the quality program must be redesigned so that measures are valid and up to date with current guidelines, selecting measures that truly add value to patient quality of care and measures that are easy to capture in practice Electronic Medical Records and selecting measures aligned with other reporting agencies.

Medicare Rules:

We would like to see additional opportunities for waivers of Medicare rules consistent with Medicare Advantage plans. We find it less administratively burdensome on our physicians when we able to streamline guidelines and processes for a population served regardless of payer.

Attribution Model:

We believe the attribution/alignment model needs to be more refined. The simplest way of doing this would be to offer a physician of choice model, offering beneficiaries an incentive to choose a PCP of record (e.g., offering enhanced benefits for beneficiaries that stay within their network). Additionally, the current attribution methodology should be modified to exclude rehab patients and beneficiaries with significant health care services delivered outside of 30 miles from the home hospital. Being an ACO in a market with lots of physician movement, CMS should allow beneficiaries to be unaligned during the payment year under certain circumstances. For example, if a PCP leaves our organization but stays within the local service area where his patients will continue to receive care from him/her it doesn't make sense that we maintain responsibility for those patients under our alignment list.

The TIN/NPI list which is used to attribute patients to our ACO is also used to capture physicians for the EHR measure and the PQRS Incentive. The multi-purpose use of this list has caused problems for our performance in the EHR measure. Specifically with respect to the EHR measure, we have physicians with a specialty in Internal Medicine that work in the inpatient hospitalist setting (i.e., hospitalists), walk-in clinic, emergency room or skilled nursing facility. These physicians are not office-based; therefore, do not have an ambulatory medical record. With the current flawed methodology, these physicians are in the denominator for this measure. We should be able to submit a list of these physicians to be excluded from the measure. The current technical specifications call for 90% of their services to be done in an inpatient setting for exclusion, it does not address additional place of service codes or factor in other criteria. This has unfairly lowered our numerator for this measure.

Financial Reporting:

We would like monthly financial/fund reporting on our ACO population. The reporting we currently receive is untimely, often times not accurate (e.g., reports are frequently recalled) and we believe CMS should consider eliminating some of the supporting detail reporting. We do not find the supporting detail useful and perhaps eliminating that could expedite the reporting process.

Utilization Reporting:

We have extensive experience working with health plans that provide monthly reporting on standard utilization metrics (e.g., Acute Inpatient, SNF and Rehab utilization). Receiving similar reports would be helpful; these reports should contain our utilization compared to ACO participants with both regional and national benchmarks. Comparative data will help us focus our efforts.

B. Population-Based Payments: CMS allows Pioneer ACOs to transition to population-based payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS 3 revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for

the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a 40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

1. **Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP?** Yes, we feel offering a difference in Part A and B reductions is important for Pioneer ACOs that choose to participate in PBP.

   Why or why not? The ability to have a different FFS reduction would provide more flexibility for ACOs with varying physician relationships. Not all participating ACOs have physicians that are part of an employment arrangement many have physicians who operate as private practice physicians. It would be important to be able to implement this at the individual provider level. The ability to do this may offer us an opportunity to negotiate with some of our preferred facilities (SNFs/Rehabs) to increase engagement without limiting us to all providers or none.

2. **Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?**

   DME should not be included in any decrease in FFS payments. Incorporating DME suppliers may require us to develop a risk sharing model with them or be required to pay claims at a later date. This would be too cumbersome with a large number of DME suppliers in our market.

3. **Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?**

   CMS should explore offering budgeted capitation arrangements with cash flow advances for infrastructure instead of population based payments. By budgeted capitation arrangement, we mean that a budget amount is set, Medicare continues to pay claims on a fee for services basis, these claims are expensed against the budget, Medicare continues to provide stop loss protection, then completes a year end reconciliation/settlement. The current model makes it very difficult for us to accurately estimate our performance in the program.

4. **Should any additional refinements be made to the current Pioneer ACO PBP policy?**
   See Question 3 above.

Section II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:

• Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;

• Give providers more tools and resources to improve care outcomes and efficiency; and

• Continue to preserve beneficiary freedom of choice in FFS Medicare.

CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

A. Transition to greater insurance risk –ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues.

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

Our Organization is not interested in full insurance risk, if defined as being a payer of claims and having to provide all the services of a licensed health plan.

As mentioned above, we would prefer a budgeted capitation model. By budgeted capitation arrangement, we mean that a budget amount is set, Medicare continues to pay claims on a fee for services basis, these claims are expensed against the budget, Medicare continues to provide stop loss protection, then completes a year end reconciliation/settlement. We are not interested in full insurance risk.

In order to consider a full capitation model like Medicare Advantage, CMS would need to limit patient access outside of their aligned ACO. Without this limitation, there is too much risk for too little control. A shared savings model with only upside potential might be more reasonable if CMS is not willing to limit access. We continue to ask CMS to consider a physician of choice model, offering beneficiaries an incentive to choose a PCP of record (e.g., offering enhanced benefits for beneficiaries that stay within their network).

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

As noted above, we are not interested in full insurance risk, if defined as being a payer of claims.

Ideally a model that allows for taking risk on all pools works best, this would be Part A, B and D. However, for Part D expenditures we currently do not get adequate data to take Part D risk. There are also too many Part D plans with varying formularies for beneficiaries to choose from in order to make this work. If CMS were to limit the Part D plans by region, this may be an option worth exploring.

3. **Are there services that should be carved out of ACO capitation?** The only services that should be carved out from ACO expenses are services received outside of the local service area. **Why?** ACOs don't have the ability manage or account for services patients seek when out of their local service area. We currently have no way of knowing when a patient is being treated outside of the service area until medical claims data is received.

4. **What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?**

In a budgeted full risk-arrangement (as defined above, not full insurance risk as defined as operating as licensed health plan) having the opportunity to negotiate ACO specific rates from our preferred facilities would be beneficial.

5. **What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk?**

We are not interesting in full insurance risk.

6. **What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?**

The Commonwealth of Massachusetts legislation, Chapter 224 of the Acts of 2012 requires Provider Organizations that have risk-based contracts with insurers to apply for and receive a risk certification. To date the regulations regarding this requirement have not been finalized; however, we anticipate the process for risk certification to be extensive and expensive for Provider Organizations. It would certainly be difficult to meet State requirements if ACOs were treated as insurance providers as there is extensive Division of Insurance Regulations that would need to be met.

7. **Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?**

We are not interesting in having full insurance risk or becoming a Medicare Advantage Organization. We do model our care management efforts for the ACO population based on our experience as a Medicare Advantage Provider Organization. If full insurance risk was a requirement for ACO participation we would be put in the position of having to negotiate with a local health plan to administer the requirements made upon us. Being in a market with several ACOs this would pose additional

difficulties in the negotiation process with health plans for providing these services. The health plans goals are to grow their Medicare Advantage membership. Having to contract with them to administer services for our ACO population for would be a conflict.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about using a local reference expenditure growth trend instead?

A capitation model that includes risk adjusted payments similar to the Medicare Advantage methodology is appropriate for capitation payment rates.

In order to sustain current ACO participants and attract additional ACOs a stable and secure benchmark approach needs to be developed. A regional/local average adjustment to the baseline benchmark trend and expenditures instead of using a national reference population may be a feasible option. CMS should take lessons learned from the past 2 years and build that into any new methodology developed.

Depending on an ACOs market, expenses may vary greatly and a national benchmark doesn't take those expenses into account. Additionally, we spend a significant amount of infrastructure dollars on the ACO program which is not factored into any current methodologies. This infrastructure is critical in order to lower medical expenses and may not necessarily be off-set by any savings achieved.

9. What are the advantages or disadvantages of different strategies for risk-adjustment?

(Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

Many risk-based payer contracts incorporate a risk adjustment/severity methodology. Incorporating a risk-adjustment methodology would align the Pioneer model with payer contracts that ACOs are experienced with and accustomed to. Most pioneers in our market place have experience with risk adjustment through the DxCG and the HCC model being used for Medicare Advantage plans. A standardized approach (when feasible) across payers is ideal when the model works. Moving to a risk-adjustment methodology would eliminate the current confusion that most ACOs experience with the complex model, especially the decedent adjustment.

10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

We believe there are opportunities to enhance benefits to ACO participants. We would support CMS offering a benefit enhancement with lower out-of-pocket costs for beneficiaries accessing care within their ACO. The current Medicare program provides no incentive for beneficiaries to coordinate with their PCP when they require specialty care. We support CMS exploring a PCP attestation for beneficiaries in upcoming years. Perhaps rolling out benefit enhancements at the same time as the attestation is rolled out would be the best way to get engagement.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

We are not interested in full insurance risk

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

We are not interested in full insurance risk

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

Irrespective of an ACO being at full-insurance risk, we believe that a physician of choice/attestation model should be the strategy moving forward for beneficiary alignment. For patients to voluntarily align with an ACO there would need to be an education campaign by CMS and ACOs on the benefits of being aligned with an ACO.

B. Integrating accountability for Medicare Part D Expenditures– An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

There are currently too many Part D providers associated with patients aligned to our ACO to establish business arrangements with Part D carriers. Not one Part D provider currently services more than 15% of our ACO population according to our limited data.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?

We certainly believe that Part D risk would be both beneficial in terms of saving money and in improving quality. In order to take risk on Part D, we would need a) the majority of our attributed patients in one PBM 2) real time data 3) the ability to pass onto the consumers some of the benefits the PBM's get from their "deals" with drug companies. We are not interesting in being a Part D plan sponsor.

If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

We do not have comprehensive Part D claims data. We are unsure if that is because of PBM reporting problems which supply this data to CMS.

C. Integrating accountability for Medicaid Care Outcomes – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

In Massachusetts, Medicaid beneficiaries are becoming more aligned with Medicaid Managed Care Organizations therefore, incorporating this population does not make sense unless we are strictly talking about those dually eligible.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes?

For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?

What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?

What are the capabilities of providers in integrating this data with electronic health records?

What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures?

Should CMS and States offer separate but coordinated shared savings arrangements to ACOs?

Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

D. Other Approaches for Increasing Accountability – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

1. **A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?**

2. **In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives.**

   Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?

   More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

E. Multi-Payer ACOs – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

1. **How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?**
2. **How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?**

   The quality measures need to be redefined to be both clinically relevant and clearly shown to improve quality of care. The measures themselves are difficult to capture data on in a consistent manner leading to variability in the validity of the data. The benchmarking methodology on which payment is based is flawed and needs to be reevaluated. This is a major drawback for new ACOs looking to participate in the program. We have already provided many examples of our concerns and would be happy to participate in further discussions. Including practicing physicians as part of the discussions on measures may help with measure selection.

MAYO CLINIC

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CMS Pioneer ACO
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Attention: Kimberly

Thank you for the opportunity to provide input regarding the evolution of ACO initiatives. In general, we continue to believe that the current ACO / Pioneer ACO program designs lack workable options for most large and medium size medical centers. While we fully agree with the three part aim of the shared savings programs, it is our sense that both programs are still too complex in their structure and requirements. They are excessively detailed and restrictive in ways that have significantly limited the number of interested groups. Key problems relate to the required structure and governance; shared savings / capitation model design, which does not provide real incentives or risk protection for efficient providers to participate; numerous and ineffective quality metrics that should be emphasizing health defined as role-functioning, health risk, mortality, personal experience and total cost of care over time; lack of beneficiary incentives to help manage their own care; excessive start-up costs and excessive administrative requirements.

Mayo Clinic recommends a simpler, more effective alternative and urges that CMS take an entirely different approach to implementing ACOs. Specifically, we suggest that CMS seek out those organizations that are already providing accountable care and directly contract with them to experiment with new innovative concepts which would help achieve the three part aim. Our recommended approach would include comprehensive proposals that link payment, delivery and financing options in terms of payment for a set of benefits.

This would require that a trusting partnership be developed between CMS and participants to utilize the best approaches to providing high quality care at reduced costs for all Medicare patients. The advantages of this approach would include:

- Elimination of profound regional variations in outcomes and spending
- Elimination of complex calculations of historical spending and savings targets
- Simplified program administration and reduced administrative costs
- Greater beneficiary choice and improved beneficiary commitment
- Greater likelihood that practices or organizations would be willing to engage with CMS as a trusted partner
- Greater likelihood that the U.S. will achieve the goals of the three part aim

We would very much appreciate the opportunity to meet to present our ideas for an innovative plan which we believe would provide CMS with needed flexibility in supporting alternative payment models in a manner that would accommodate increased provider participation,

reduced Medicare spending and enhanced patient outcomes, while maintaining only the minimum necessary administrative provisions required by regulation. Thank you for considering our request. We look forward to meeting with you to discuss these concepts in more detail. Please contact me at 507-284-4627 or grousky.ronald@mayo.edu if you have any questions.

Very truly yours,

Ronald Grousky
Vice Chair, Revenue Cycle
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CC: Kathleen Harrington, Chair, Government Relations, Mayo Clinic
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February 28, 2014

The Honorable Marilyn Tavenner, R.N.
Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Request for Information on the Evolution of Accountable Care Organization (ACO) Initiatives at CMS

Dear Madam Administrator:

On behalf of McKesson Corporation ("McKesson"), I am pleased to submit comments to the Centers for Medicare and Medicaid Services ("CMS") on the request for information on the evolution of ACO initiatives at CMS. McKesson's responses to specific questions have also been submitted electronically to the Center for Medicare & Medicaid Innovation (CMMI) through the CMS website.

For more than 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. As the largest health information technology (IT) company in the world, we are actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce the cost and variability of care and advance healthcare efficiency.

McKesson has decades of experience serving the health IT needs of the largest and most diverse provider customer base in the industry, including 52 percent of our nation's hospitals, 20 percent of all physician practices and 25 percent of home care agencies, which support more than 50,000 home care visits annually. McKesson is also the nation's largest distributor of pharmaceuticals as well as the leading supplier of biotechnology and specialty pharmaceutical products and services for providers and patients.

For decades, McKesson has partnered with customers to deliver unique solutions that enable payers, providers, consumers and employers to transform the business and process of care. McKesson helps organizations bolster their care management processes, control chronic health conditions, guide level-of-care decisions, determine risk, forecast future needs, and manage their claims payment cycle.

McKesson provides care and claims management solutions to the top 25 payer organizations, 92 percent of Blue Cross Blue Shield plans and more than 70 percent of our nation's acute care facilities. McKesson also provides care management services to state Medicaid programs and commercial payers; more than 10,000 providers use our analytics tools to manage population health and risk.

Today, our extensive experience across healthcare settings and technologies includes assisting our customers as they serve seven million individuals who receive care in accountable care arrangements. Based on our expertise in helping our customers plan, implement, and manage populations in commercial plans and in ACO models within the Pioneer ACO, Medicare Shared Savings Program and Medicare Advantage Programs, McKesson offers the following recommendations in response to selected questions posed in the CMS request for information.

McKesson supports the efforts of CMS to explore various payment and service delivery models through CMMI. We applaud the Agency's goals to promote innovation, improve quality of care and reduce costs in the healthcare system.

Section II: Evolution of the ACO Model

A. Transition to greater insurance risk –

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

Yes, McKesson recommends that CMS offer ACOs capitation with insurance risk, as this might encourage ACOs to align their care models, processes, strategies and incentives with their other value-based programs.

Potential risks associated with offering capitation with insurance risk may include poor performance which could create financial deficits, particularly for those ACOs with small numbers of patients. CMS might mitigate this risk by limiting offerings such as capitation-based programs to ACOs with a minimum experience level of managing risk and a track record of success.

Because most large and small ACOs are inexperienced in managing risk, we believe that reinsurance would be critical and mandatory. A CMS-facilitated reinsurance program that pools risk among ACOs could make reinsurance more affordable and increase the probability of success of the program.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

McKesson believes that ACOs should be responsible for all expenses with the exception of (1) out-of-area care and (2) certain high cost drugs, as long as a CMS-facilitated reinsurance program exists. Out-of-area care, particularly during the winter travel season, presents challenges for typical CMS ACOs as they have little, if any, opportunity to influence the care their patients receive during this time period. We recommend that CMS consider a broader reciprocal network of participating programs in order to reduce the potential for out-of-network expense exposure.

McKesson recommends that certain categories of infrequently-prescribed, high cost drugs for rare diseases also be excluded from full insurance risk, as these drugs can have a disproportionate impact on a capitated budget, even among large populations. However, we recommend that CMS include Part D drug costs within the insurance risk, as providers have the ability to significantly influence and control these costs through therapeutic substitution and outcome-driven prescribing behavior. Similarly, at-risk providers bearing Part D risk would be further incented to focus attention on patient adherence and compliance to medication therapy. While adherence may increase utilization, the risk of non-adherent complications and co-morbid conditions offsets the potential rise in utilization driven costs.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

ACOs are most successful when providers can coordinate care and optimize the use of resources across the full continuum of care, which includes the post-acute phase such as skilled nursing facilities (SNFs), rehabilitation facilities, long term care facilities, hospice, and home care organizations. ACOs can promote efficiencies by entering into preferred arrangements with such facilities and organizations. For example, an ACO could select a SNF as a preferred facility based on criteria such as superior performance metrics, the ability to provide the ACO with a rate reduction, or participation in risk-sharing. Such preferred arrangements, which should include rate discounts, sub-capitation, and risk-sharing in the form of performance-based payments, are already

in place in some locations. McKesson recommends that CMS consider revising regulatory requirements which arbitrarily limit care-setting transitions and increase the costs of care, such as the three-day acute hospitalization requirement for SNF eligibility.

Additionally, ACOs must have the complete set of paid prescription claims to assess total care and patient adherence to prescribed medications and appropriately manage quality reporting and the cost of care in a full insurance risk model. We recommend that CMS ensure that ACOs are provided with the complete set of paid pharmacy claims on at least a monthly basis. The prescription fill data should be made available as near to real-time as possible.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

Regulations which establish minimum financial reserve requirements may make it difficult for ACOs, especially those with a small number of patients, to meet state licensure requirements. Mandatory ACO participation in a reinsurance program could mitigate the risk of waiving state licensure requirements. The actuarial instability of the ACOs that may need this reinsurance the most would make the purchase of reinsurance on the open market expensive, if not prohibitive. As suggested in our response to Question 1, a CMS-facilitated reinsurance program that pooled risk among such ACOs could make reinsurance more affordable and encourage broader participation. Another risk mitigation strategy for ACOs would be the use of a selective withhold program, which are generally disliked by individual providers.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

The type of financial system needed would depend on the mechanism by which the capitation is administered. If an ACO were paid the full capitation rate, it would need systems to pay claims, monitor fraud and abuse, allocate other payments, and carry out additional functions. If a "budgeted capitation" model were used, where CMS continues to pay claims and periodically settles with the ACO, ACOs would need a mechanism to receive direct payments to operationalize sub-capitation and other similar special arrangements. Under this model, CMS would pay claims with or without a "withhold", a percent of payment that is held back. If a withhold program were in place, CMS would need to establish frequent settlements for ACOs to manage and maximize cash flow.

We suggest CMS also consider the formation of regional Third Party Administration (TPA) networks. These networks could lower the administrative overhead costs associated with the management and payment of claims by including provisions for fraud and abuse monitoring.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

Based on our experience with ACOs across the country, using a national trend for benchmarking has limitations due to significant variations in local growth trends. It would seem inappropriate, however, to reward ACOs that are contributing to inefficient markets. McKesson recommends that CMS initially use local trends for regional benchmarking and gradually migrate to a blended local/national approach in markets where local trends exceed national trends.

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

McKesson believes that demographic risk adjustment is insufficient for the determination of capitation rates. We recommend an illness burden type of methodology, such as the diagnostic cost group-based hierarchical condition category-risk adjustment factor (HCC-RAF) used in the Medicare Advantage program. In order for provider-based ACOs with sicker patients to succeed under a capitation model, the illness burden should be accounted for in the risk adjustment methodology.

The current HCC-RAF model used by the Medicare Advantage program could be improved in a way that decreases the administrative burden on provider organizations. Today, if a patient has a permanent chronic condition (e.g., an amputation), a provider is required to code this condition on a claim every year. Unnecessary annual coding for chronic conditions, which is performed only to achieve the accurate risk adjustment factor inefficiently, consumes resources, increases administrative costs and reduces resources that might be better directed toward patient care. We recommend that the risk adjustment program retain relevant claim information year over year.

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

Based on our experience, the coordination and management of care across the continuum are key drivers of success for the ACO model. This is best achieved when all care, or as much as is possible and appropriate, is provided and managed by ACO providers. Some of the benefits of in-network care include: improved communication and care coordination among providers, fewer duplicative tests, and management programs focused on continuity of care. The program's current commitment to the open access model makes it difficult for ACOs to retain patient care within their networks, which makes it more challenging to realize these benefits. An important approach towards resolving the open access challenge is to incentivize patients to select ACO or ACO-affiliated providers. Co-pays for care delivered by providers that are not part of the ACO and/or differential co-pays that incent patients to receive their care from ACO providers are well understood and supported by patients and would be a simple way to address this problem.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

No, in a fully open access program, it would be inappropriate to permit a patient to elect alignment with an ACO where the patient sees one specialist once a year and then receives comprehensive care for an expensive chronic illness at a tertiary facility within another ACO. Similarly, it would be inappropriate for a patient to select an ACO associated with a tertiary academic facility "just in case" he or she suffers a significant acute illness while receiving all ongoing, "longitudinal" care from local providers in a different ACO.

The disadvantage of allowing patients to voluntarily align themselves to an ACO is that they will not fully benefit from the quality improvement programs provided by the ACO which actually delivers their care. This can be avoided by the implementation of either a minimum threshold criteria for a patient to self-select an ACO or a patient incentive program. In most cases, a patient incentive program will incent a patient to select the ACO where he or she plans to receive the majority of healthcare.

B. Integrating accountability for Medicare Part D Expenditures –

1. **Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?**

ACOs can effectively control ambulatory drug costs and simultaneously improve care. Some provider organizations have implemented drug management programs based on sophisticated software tools and, subsequently, have achieved excellent clinical and financial results. These programs are most successful when implemented across all of an organization's risk-based arrangements. Physicians should be incented to provide the most cost effective care based on evidence-based practices and not payer-specific requirements. By using a uniform approach to manage all members of its patient population, the practice can most effectively address care disparities, reduce care variation, reduce administrative overhead, and achieve optimal clinical and financial performance.

Timely prescription data is the foundation of drug management programs, and the inaccessibility of this data is a significant barrier to success. In our experience, limitations on the availability and uniformity of such data is typically driven by a lack of data sharing based on commercial and competitive interests and/or perceived data ownership rights. This limits the provider's ability to fully understand a patient's medication consumption and compliance and, subsequently, influence patient behavior.

CMS could mitigate this barrier by requiring that each ACO be provided with a paid pharmacy claims file at a specified frequency. To be clinically useful, this file should be shared in a standard format for interoperable systems to exchange and be provided at least monthly. More frequent exchange of pharmacy claims files would add clinical value. We suggest that all pharmacy claims and, where possible, prescription fill data be made available to the ACO managing the patient. The management of patient adherence and compliance to prescribed therapies would be significantly improved with the timely delivery of a complete set of paid prescription claims.

2. **Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?**

Yes, ACOs should be permitted to assume the risk for most drug costs. They are in the best position to assume and manage that risk given their providers' direct relationships with the patients for whom they write the medication prescriptions. We have also found that providers respond best to drug management programs, such as substitution programs, when they are administered by their ACOs and extended across all their patients, rather than directly administered by a payer.

ACOs must have the complete set of paid pharmacy claims to assess total care and patient adherence to prescribed medications and to appropriately manage quality reporting and the cost of care in a full insurance risk model which assumes accountability for Part D expenditures. We recommend that CMS ensure that ACOs are provided with the complete set of paid prescription claims.

A unified expenditure target or capitation budget can be established with a unified risk adjustment methodology assuming that the risk adjustment methodology would be based on the illness burden. It would be optimal if certain high cost and rarely prescribed drugs were carved out of the providers' risk, as we commented in response A2.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

Based on our interaction with our customers, we believe that ACOs should be provided with a paid pharmacy claims file and, where possible, prescription fill data on at least a monthly basis. To be clinically useful, this file should be shared in a standard format for interoperable provider systems. The provision of this data on a regular basis is critical to the risk-bearing providers' ability to effectively manage drug costs and to drive quality improvement and safety related to drug prescribing.

As we mentioned in our response to the previous question, ACOs must have the complete set of paid prescription claims to assess total care and patient adherence to prescribed medications and to appropriately manage quality reporting and the cost of care in a full insurance risk model. We recommend that CMS ensure that ACOs are provided with the complete set of paid pharmacy claims.

Provider organizations either have or will soon have programs leveraged by automated software solutions that help manage prescribing practices in a uniform process across all their patients that are in risk arrangements. Paid pharmacy claims in a recognizable format would be needed to support these standard programs. The availability of this data and the rights to the use of this data should not be unduly restricted.

There is also the potential to gather information on prescription claims paid out of pocket as well as prescription claims paid but not picked up at the pharmacy. There will typically be a lag time of up to 14 days for the reversal of the pharmacy claim associated with the prescription that was not picked up by the patient.

We recommend that CMS ensure that ACOs are provided with a complete set of paid prescription claims.

C. Integrating accountability for Medicaid Care Outcomes –

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

Healthcare is most effectively delivered when a provider system cares for all of its patients under a similar accountability and payment model. This allows for the internal alignment of incentives and uniformity of processes. This also allows organizations to develop scale, spread the risk across a large population and make the necessary investments to support the needed management processes for care coordination and infrastructure, including IT systems.

The institution of income-based parameters under the ACA has improved the historically "difficult to manage" Medicaid population. The "churning" of enrollees is now limited to those who lose coverage due to avoidable reasons, such as the failure to renew coverage. ACOs with Medicaid enrollees should consider support mechanisms to assist enrollees in their application process.

In order for blended population programs to be successful, outcome metrics and data should be similar among programs while allowing for demographic and population nuances, thereby driving operational efficiency. Due to the different risk and cost profiles of Medicaid and Medicare populations, especially among the dual-eligible population, an appropriate risk adjustment methodology for capitation determination should be in place. This methodology should incorporate factors such as the illness burden, a behavioral health multiplier and historic utilization patterns. Dual-eligible populations should initially be carved out from participation in ACO models due to the significant differences in their needs and utilization profiles.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-

Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

It is important to implement standard processes and operations to achieve best practices, especially across large populations of patients. We suggest that most patients be included in an ACO without regard to demographics, history or other factors. Some of these populations have significantly disparate risk profiles, so an appropriate risk adjustment methodology for capitation determination should be in place to include the illness burden, a behavioral health multiplier and historic utilization patterns. Different risk adjustment models normalized for different populations, including demographic factors and payer history, may be required.

Dual-eligible populations should be initially carved out from participation in ACO models due to the significant differences in their needs and utilization profiles.

3. **What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?**

To the extent possible, states should align with the CMS ACO programs or work collaboratively on program design to achieve that alignment. This would permit provider organization alignment and promote standardization and harmonization between common processes and programs which would drive efficiency and better outcomes. Areas for such alignment include contract models, quality metrics, reporting on outcomes which include measure definitions, formularies and data file standards. It would also be advantageous for states that sponsor health exchanges to align with CMS ACO providers to ensure optimal efficiency of the delivery network while providing a potentially more balanced risk pool.

4. **What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?**

ACOs recognize that data management and analytic capabilities are essential to their success and implement and upgrade their systems to support changes in operational requirements. ACOs recognize the importance of paid claims data which provide a comprehensive view of the care continuum and contracted network. Claims provide the only data source to determine care delivered by "out of network" providers or those not associated with the ACO.

ACO organizations also value clinical detail and timeliness of data generated by EHRs. However, it is not possible to support the needs of an ACO exclusively from the data within an EHR. Additionally, claims-based data and its inherent lag time create barriers to timely patient intervention. Because of these limitations, ACOs require enterprise registry platforms which allow for the integration of all necessary management data.

McKesson has extensive experience in the acquisition and aggregation of disparate data sources, which has proven essential to our ability to support our ACO clients. Despite best efforts, commercial and competitive barriers to interoperable data remain. Today, some commercial vendors are reluctant to partner in the provision of accessible and codified data. We recommend CMS consider incentives to facilitate the availability of all necessary data for the effective aggregation and analysis of patient information.

5. **What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings**

arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

Based on our experience, the demands of Medicare and Medicaid populations differ significantly and would be best suited to coordinated, rather than unified, shared savings arrangements. However, alignment of program reporting metrics would provide administrative simplifications and operational efficiencies for ACOs that care for both populations.

D. Other Approaches for Increasing Accountability

1. **A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?**

We believe that geographically aligned populations do not pose additional challenges as long as the plans under which they are covered are programmatically aligned, appropriate risk adjustment is performed with respect to their capitation, and quality metrics are appropriate to all populations. In general, most quality metrics should be applicable to all populations. However, there are certain measures for some populations, such as pediatrics, dual-eligible beneficiaries and other special groups, that would need to be considered and incorporated.

E. Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

Providers will be most successful when they can achieve internal alignment and be free of conflicting payment model objectives, especially with respect to incentives related to the volume of patient services. In general, for an organization that has adopted accountable care, the greater the proportion of their patient population under a risk- or value-based contract, the better. Reaching a critical number of patients receiving care under an accountable care model allows provider organizations to focus on their care delivery strategies rather than revenue generation. ACOs can adopt universally applied care processes, care coordination programs, physician profiling and incentive programs.

Organizations we work with that are experienced in managing risk have learned that the most optimal approach is to implement programs across all payers. To achieve efficiencies across the geographic communities for which the physician is responsible, McKesson recommends that the same care coordination, care transition, and physician profiling programs be in place across the ACO. Organizations want to support such programs with single all-payer reporting and analytic tools and view these as critical to their success. These ACOs also want single software solutions to support all their payers in a consolidated manner. These consolidated resources enhance management and increase efficiencies. More importantly, clinicians seek a single work flow across all payers to improve the efficiency of their practice and prefer to see consolidated patient and performance reports.

CMS can support the success of these organizations in a multi-payer environment and encourage their adoption of other payers' risk arrangements by recognizing their needs, as described above. Specifically, it is important for CMS to understand that ACOs do not want to utilize CMS-specific management reports to manage their populations, as this does not support their uniform payer reporting. ACOs need patient data to populate their analytic and clinical registries and care management software solutions. CMS and other payers can best meet this need by providing complete paid medical and pharmacy claims data frequently, consistently, and with as

little disruption as possible. The likely result is that organizations will be better positioned for success and encouraged to enter into more accountable care type arrangements.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

CMS and other payers should consider several areas of quality reporting improvements. First, we urge CMS to harmonize quality measure requirements across payers and programs. This should include the alignment of the measures selected for each program, including the ACO initiatives. We also urge CMS to include the technical alignment of the quality measure specifications, reporting periods, and reporting methods, format and standards. CMS has begun this effort for some federal programs, although still more is required to minimize the reporting burden on providers.

This alignment of quality requirements should also extend beyond CMS to other payers. One approach CMS could consider and potentially adopt would be to focus on guidelines promulgated by national organizations, such as the National Committee for Quality Assurance (NCQA), and those endorsed by the National Quality Forum (NQF). Another approach would be to form a collaborative among payers to agree on a common set or menu of measures, ideally in collaboration with provider organizations. This process should include attention to the feasibility of data collection to adjudicate selected quality measures. The recognition of the complexity of clinical data collection across large networks with disparate ambulatory clinical IT systems must be incorporated into this process.

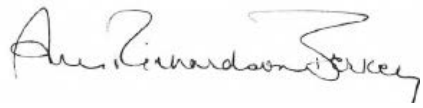
Conclusion

In closing, McKesson supports the efforts of CMS to promote innovation, improve quality of care and reduce costs in the healthcare system. As CMS reviews the next steps in the evolution of ACO initiatives, McKesson recommends that the following be considered:

- Offer ACOs capitation with insurance risk and require participation in an affordable reinsurance program for all ACOs, particularly for ACOs with fewer patients;
- Consider a broader reciprocal network of participating programs in order to reduce the potential for out-of-network expense exposure;
- Explore a capitation rate-setting model that gradually blends local and national trends in markets where local trends exceed national trends;
- Improve the current HCC-RAF model used by the Medicare Advantage program in a way that reduces the administrative burden on provider organizations;
- Resolve open access challenges with the use of patient incentives to select ACO or ACO-affiliated providers through the use of co-pays;
- Require that all pharmacy claims and, where possible, prescription fill data, be made available to ACOs on a frequent (at least monthly for paid claims) basis in order to ensure optimal and timely management of patient adherence and compliance to prescribed therapies and cost of care;
- Introduce incentives that would facilitate the availability of all necessary data for the effective aggregation and analysis of patient information; and
- Align quality measure requirements across payers and programs including ACO initiatives.

We appreciate the opportunity to comment on this request for information. Should you have any questions, please contact me at 415-983-8494 or ann.berkey@mckesson.com.

Sincerely,



Ann Richardson Berkey

A. **Transition to greater insurance risk** –ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues.

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries? Yes. MCNT is very interested in moving to a risk model as we believe this is the best opportunity to coordinate care, increase quality and reduce unnecessary utilization.
2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries) We want to participate in Parts A and B, but not D. Part D requires additional resources/expertise and adds a layer of complexity to the program administration.
3. Are there services that should be carved out of ACO capitation? Why? Similar to Medicare Advantage—hospice, ESRD. We believe it is very difficult to determine an appropriate capitation amount for these conditions.
4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population? Initial agreements for ancillary and specialist providers would be fee for service but we would like to move to pay for performance agreements. Specific metrics will all be related to quality of care and will allow the downstream providers to share in savings related to the provision of the right care, at the right time in the right setting.
5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk? The regulatory and compliance framework would be very similar to Medicare Advantage with the exception that ACOs should be allowed to provide reasonable inducement for patients that are compliant with completing quality metrics/ self-management goals etc. Patients often need a minimal incentive to participate in their care and small tokens often provide that incentive.
6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse

laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population? Financial reserves associated with risk-bearing are likely to be a significant struggle for many ACOs.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk? Operating in a full-risk environment will require significant infrastructure. Many services can be outsourced such as claims payment or utilization management with the ACO maintaining oversight responsibility. Others, such as member services and credentialing will require additional resources on the part of the ACO. In either case, additional oversite personnel are likely to be necessary.
8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead? We believe regional rates more accurately reflect the needs of the population. Some markets are more mature than others so markets such as Florida with a greater percentage of MA market share would expect to have a different benchmark than a less mature market like Dallas. Additionally, while we recognize the need to normal costs, benchmarks must include catastrophic cases as these cases have significant cost impact on the ACO.
9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.) Demographic risk adjustment strategies will pick up regional differences in the population such as a higher incidence of heart disease or diabetes in certain populations. The MA plans do a better job of truly identifying the risk code associated with an individual patient.
10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid? Structuring copayments to incent patients to see their primary care physician will result in the best outcomes, highest quality and appropriate savings. Copays should be dropped for primary care, higher for urgent care and highest for emergency room to discourage patients from using the urgent care clinics and emergency rooms for primary

care services. Specialist co-pays should be higher than PCP, but still affordable for the patient.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards? The ACO full risk program must be structured such that ACOs are not rewarded for withholding care. This can be accomplished through monitoring quality metrics. Sub-contractors in a fee for service environment must also be monitored to ensure they are not over-utilizing. This can be accomplished by the ACO requiring authorizations for some services, monitoring costs (by specialty/by provider) and addressing any potential problems as they are identified.
12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection? Precautions for full risk ACOs should be similar to MA plans. For a model in which a patient must pick an ACO this becomes more important. Protections include the use of licensed sales agents just like a MA plan would require.
13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution? Yes—in a full risk environment, patients should be allowed to choose their ACO whether they have been previously aligned to this group or not. There are a number of factors that go into this decision and patients should not have to stay with a PCP simply because they have previously established care with that provider. The most simplistic example is simply because the patient moves and the previous provider is no longer convenient. Claims based attribution also makes it more difficult to engage patients and can result in lower scores for quality etc.

B. **Integrating accountability for Medicare Part D Expenditures**– An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation. MCNT is not interested in taking risk for pharmacy at this time.

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?
2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?
3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

C. **Integrating accountability for Medicaid Care Outcomes** – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes. MCNT has developed our processes around a senior population. We are not focused on a younger population and are not interested in taking risk for the Medicaid population.

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?
2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?
3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting

model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic

health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

D. **Other Approaches for Increasing Accountability** – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C. MCNT would potentially be interested if CMS/HHS requires all plans in the exchange to use CMS criteria. Managing multiple criteria for each populations group makes it very difficult for ACO to administer.

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?
2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

E. **Multi-Payer ACOs** – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi- payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

1. How can CMS encourage the adoption of ACO contracts among other payers

of Medicare ACOs?

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

MICHIGAN PIONEER ACO

Accountable Care Organization

Response to CMS Request for Information

Michigan Pioneer ACO is pleased to submit comments on the RFI issued by the Centers for Medicare and Medicaid Services (CMS) regarding the Evolution of ACO Initiatives at CMS.

Michigan Pioneer ACO is one of the original 32 participants in the Pioneer ACO Model. Our ACO has 179 physicians with aligned beneficiaries, and consists of 124 independent physicians in private practice, 13 employed by our affiliated hospital system, the Detroit Medical Center (DMC), 25 faculty practice physicians affiliated with the Wayne State University Department of Medicine, and 17 physicians affiliated with a practice focusing on home-based patients.

Michigan Pioneer ACO serves primarily a safety net population of patients in the City of Detroit and the surrounding area, which presents its own unique set of issues. Nevertheless, we have had success in realizing shared savings in our first year of operation, and it appears that we will be successful in our second year as well. We attribute our good fortune to a variety of clinical programs that we have instituted to serve our aligned beneficiaries, focusing primarily on care transitions and post-acute opportunities to improve care coordination and lower the overall costs of treating our patients.

We have approximately 18,500 aligned beneficiaries that we are serving in our third year of the program. Out of these 18,500 aligned beneficiaries, we have approximately 6,000 beneficiaries that also are covered by the Medicaid program, and therefore are "dual eligible's."

Because of our large number of dual eligible beneficiaries, we will focus our initial response to the RFI on Section II, Evolution of the ACO Model, Subsection C, Integrating Accountability for Medicaid Care Outcomes. Before doing so, we would like to make some general comments regarding the Pioneer ACO Program that we hope CMS will consider carefully no matter what direction it will take.

General Comments:

1. One of the three major goals identified by CMS for its ACO initiative has been to preserve beneficiary freedom of choice. Freedom of choice, while desirable, means that beneficiaries may not be invested in receiving care from an ACO. While patient engagement is an important responsibility of an ACO, our opportunities for patient engagement are limited, given the number of different providers Medicare patients visit in any one year. It is extremely difficult to control utilization appropriately without approval ability, particularly as it relates to testing and procedures. While we understand CMS's reluctance to make such a significant change in the fee-for-service structure of the current Medicare program, to the extent it is not willing to do, it must consider other alternatives to provide ACO's the tools to better control utilization. Many of the following comments relate to providing those additional tools.

MedPac and others have discussed beneficiary incentives as a means of ensuring that appropriate care is delivered in an in-network program. For example, lower cost-sharing for in-network services could increase engagement with the ACO. Supplemental insurance for beneficiaries tied to participation in an ACO is another suggestion made by MedPac to increase loyalty to ACO primary care providers. Greater flexibility to provide patient incentives to remain in-network should be considered as an integral part of any program to expand or modify the current ACO initiative.

2. Consideration also should be given to the alternative of instituting an enrollment methodology for the program. The enrollment methodology could be accompanied by limitations on receiving out-of-network services, as long as adequate in-network providers and services are available. Beneficiaries would be bound to the ACO for a period of time, but with appeal mechanisms in the event care is considered inadequate or inappropriate.

Complete freedom of choice, with its high resultant beneficiary turnover, limits incentives for ACO providers to concentrate on longer-term measures that in the short run will cost either the Medicare program or the ACO in the form of additional resources required, but in the medium to longer term will be beneficial for both the ACO and the Medicare program. Chronic care patients such as those with progressive diabetes or requiring renal dialysis, consume significant resources as their diseases progress, and often, with the right interventions, such progressions can be slowed or even reversed, but unfortunately there are insufficient incentives in the current system to take the actions required to optimize longer term success.

3. As long as an attribution methodology is continued for the ACO program, we believe it is necessary to permit beneficiary attestation in order to ensure a continuity of care from year to year. Our ACO has experienced a very significant turnover of

beneficiaries (approximately 30% from PY 1 to PY 2 and approximately 35% from PY 2 to PY 3). We have a number of beneficiaries who receive very intense care management services each year, and many of them were no longer aligned with us for one reason or another between PY 1 and PY 2 and again between PY 2 and PY 3. Not only is it awkward to tell these patients that they are no longer eligible to receive the extra care management services, but it is a real disservice to those patients who find real benefit to the services provided (which are not billed to the Medicare program). Initially we were told that because of the high turnover of beneficiaries expected, there would be beneficiary attestation available to the ACO in as early as PY 2 and yet this has not been implemented.

We believe the lack of beneficiary attestation is a serious shortcoming of the program and should be implemented as quickly as possible, preferably for PY 4.

4. ACO's have only limited means to obtain notification of out-of-network services being provided to their beneficiaries. In our case, the beneficiaries aligned with the Michigan Pioneer ACO receive between 50% and 60% of their services from out-of-network providers. The Detroit area is a very competitive environment, and there is very little sharing of information among hospitals and other providers. There are fledgling efforts at a local HIE system, but currently there is no significant real-time notification of out-of-network services. CMS could effect a significant "game-changer," in terms of boosting ACO success, if it were to address the notification issue. When a beneficiary visits an ER or is admitted at an out-of-network facility, there must be a method by which the out-of-network hospital can be required to notify the ACO that its beneficiary is there or alternatively, when CMS receives any type of notice for eligibility purposes, it should provide that notice to the ACO.

Without the ability to control where our patients go, and without the ability to find out where they are, the ACO is significantly limited in what it can do to coordinate and improve care provided to its beneficiaries.

5. The existing waivers that are applicable to ACO providers limit the incentives that can be provided to beneficiaries to in-kind items or services and prohibit the waiver of copays and deductibles. This significantly limits appropriate incentives from being provided. For example, there are a number of beneficiaries (CHF and COPD patients) that could benefit from more frequent visits to providers, but often balk at the additional co-pays and deductibles for which they will be responsible. These visits, however, can prevent future hospitalizations, which are much more costly to the Medicare program. With the ACO being at risk for total spending of our patient population, we should have greater flexibility to influence the receipt of some services (e.g., primary care visits) that we believe will reduce the need for other, more costly services such as future

hospitalizations. We appreciate that the Pioneer program was willing to embrace a waiver of the three day hospitalization requirement for the receipt of Medicare SNF services, as an example of how flexibility can and should be used to achieve desired outcomes. Similarly, waivers of copays and deductibles can be an appropriate method of influencing patient behavior and the governing body of the ACO should be given the right to make a reasonable determination that it is in the best interests of the program to provide the waiver.

Cash inducements also can be useful in incentivizing Medicare patients to achieve quality goals (e.g., coming in to see their primary care physician, or obtaining necessary diagnostic testing such as a1c's or lipid testing) or in helping them to subsidize the costs of necessary medications. While we appreciate some of the concerns that underlie the limitations of the current waivers, we believe they limit the scope of what can be done in an appropriate manner to help ensure that services are received that will have an overall positive effect upon the program and our aligned beneficiaries. When the Pioneers such as ourselves are at risk for total expenditures under Part A and Part B, we have the same interest as CMS in ensuring that waivers are not used in an inappropriate manner to increase expenses to the program.

6. One of the big roles that CMS can continue to play is to speed up the adoption of uniform IT platforms of care across the country. While we recognize that there may be other agencies involved, there is a particular issue that CMS could address, which again would be a "game changer" in terms of ACO success, but would have ramifications far beyond ACO's.

Currently, there is no "source of truth" in terms of medication reconciliation. A patient leaves the hospital and may or may not bring with her to the primary care physician the complete list of medications reflected in the hospital's discharge medication instructions. The physician also may alter those medications and note those alterations in the medical record, but there is nothing guarantying that the updated medication reconciliation report then is available to the hospital, the specialist, the post acute facility, the home health nurse, etc. Medications can be added or subtracted at a number of different places in the system, and the burden is on the patient to keep track of all medications and to reflect that when she sees each provider, unless there is a closed system of care or unless there is a completely implemented HIE in place among all the different providers that patient might encounter. At least in Detroit and with regard to our ACO patients, neither of the latter two alternatives are in place and therefore the patient (who often is the frail elderly) or the patient's caregiver is the one who has the burden of understanding and keeping track of the different medications and dosages.

CMS could establish a medication repository that all providers must use for Medicare patients to reflect all medications prescribed for those patients. With today's technology,

appropriate provisions could be put in place both to identify who has access to the system and who can and does make changes to the medication list. We believe that will be of tremendous value in terms of care coordination and the savings will more than offset the cost of establishing such a platform.

7. We applaud the team at CMS with whom we have been working as being truly dedicated to the objectives of the program and working with the Pioneers in a manner designed to achieve the overall goals of the model. We feel we have a good working relationship with them and one that has helped to ameliorate some of the disappointments we have had regarding certain issues such as data reliability and integrity.

While we have had success in the program, we note many who have not, and even in the case of those of us who have had success, the cost of providing the care team and other resources necessary for our efforts has to date exceeded the shared savings realized. Therefore, the long term sustainability of this effort is in doubt.

We believe that the current model as well as any modifications to it need to have enough of a return associated with it to ensure long term success. We would be willing to work with CMS to help achieve this goal.

8. We note that the Pioneer methodology is very complex and difficult to both understand and implement. It is based on a retrospective benchmark computation, that uses actual trend figures from a reference population. Because of its complexity, the lack of accurate and precise data received, and the retrospective benchmark, it is almost impossible to forecast with any accuracy the financial results of the program. We believe that a projected trend, such as the one used in the Medicare Advantage program, may be less precise, but is better for those of us who need to budget our use of scarce resources on a prospective basis.

9. As noted above, the physicians in our ACO primarily are independent practitioners, not employed by the ACO or our affiliated health care system, the DMC. In our experience, we have found a number of those physicians who are not sufficiently motivated by the financial incentives currently offered by the ACO to take the time and make the efforts required to fulfill the various quality and other requirements imposed upon them by the ACO. Where that happens, the ACO may terminate the physician's participation in the program, but the ACO is nevertheless responsible financially for the aligned beneficiaries of that physician. There should be a method by which the ACO can be released from any further responsibility for those beneficiaries, since it has no control over them once the physician leaves the program. This is particularly a problem with new physicians that are recruited into the ACO and is exacerbated by the requirement that they must sign up for participation in July of the year preceding the effective date of their participation, but really do not have a complete idea of what is required of them until the

performance year begins. There should, at a minimum, be a grace period of six months by which the ACO could terminate physicians and not be required to remain responsible for the terminated physicians' beneficiaries.

With the foregoing comments in mind, we would like to address the specific questions noted in the RFP relating to Medicaid Care Outcomes.

C. Integrating accountability for Medicaid Care Outcomes

1. *Should ACO's caring for Medicare outcomes also assume accountability for Medicaid outcomes?* Dual eligible beneficiaries often have complex, interrelated needs and historically have had access and coordination issues and have suffered poorer outcomes than other Medicare groups. These beneficiaries consume a disproportionate amount of Medicare spending. Consequently, applying the ACO concept to this population could significantly enhance the opportunity to improve care and lower costs. One reason is the bifurcation of coverage and responsibility. Allowing ACO's to assume accountability for Medicaid outcomes as well as Medicare will encourage the delivery of integrated care and should be considered.

Numerous studies have shown that at least with respect to the Medicare Advantage program, it is more difficult for plans with dual eligible beneficiaries to attain quality outcomes and measures. Therefore, the same quality benchmarks applicable to a pure Medicare population should not be applied to a population of dual eligible's, even if the same standards are applied.

2. *What populations should CMS prioritize in integrating accountability for Medicaid outcomes?* Many states are in the process of implementing demonstration programs for the dual eligible population and the subgroups of duals that are part of these efforts across states vary. CMS should allow ACO's to propose whether they would serve all duals or a specific subset(s) defined by CMS. ACO's should not be required to accept accountability for all those in a specific geographic area because some of these may be enrolled in MA plans and Special Needs Plans (SNPs) who have accountability, unless the model is a provider-led community ACO as indicated in Section D2. ACO's should be allowed to draw in new beneficiaries as well as be accountable for those they have treated historically.

It also is difficult to answer this question in the abstract, as each demographic subgroup carries its own unique risk and care coordination difficulties. Decisions on participating

in specific care models would depend upon the level of risk assumed. ACO's taking on risk would need to sufficiently coordinate alignment with behavioral health providers.

3. *What should be the role of States in providing appropriate incentives to foster the development of an integrated care system?* States can set Medicaid policy and contract requirements to provide financial incentives for integrated care and can set performance requirements. In this regard we note that many states are currently engaged in completing planning cycles for the State Innovation Models. In doing so they have developed model designs and testing plans. The evolution of the ACO concept should incorporate specific state approaches to delivery system and payment reform. State infrastructure varies significantly and the answer to the question of whether states have adequate resources to support a collaborative ACO initiative will be state specific.

4. *What are the current capabilities of ACO's and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?* Our ACO only receives Medicare FFS data from CMS. While generally we have learned both the capabilities and limitations of this data, the data is limited in many key respects. For example, we only receive pharmacy Part D data on a portion of our patients. Moreover, this data is claims data, and is no substitute for real time data that is useful in the care delivery process. In that regard, while we receive real time notification from our affiliated hospitals when patients visit them, we cannot and do not know when our aligned beneficiaries visit out-of-network facilities. This continues to be one of the largest impediments to making progress on care delivery and care transition, as noted in our general comments (General Comments, Paragraph 4 above).

We have no experience with the receipt of Medicaid data, and do not know whether it is as complete as the Medicare data we receive, and what challenges will be presented by that data. While we have specifically requested receipt of that data on our dual eligible population, to data we have made no progress on receiving that information.

Because of the large number of private practice physicians in our ACO, we do not have a single EMR in use; rather, there are over 15 different EMR's that our physicians utilize. This makes the integration of data highly problematic. While we have made some progress over the two year period we have been in operation, the lack of an effective operating HIE in our area has made our care coordination model very difficult to implement in practice. CMS should consider additional funding for information system capability for those organizations participating in broader risk programs, such as those for dual eligible beneficiaries, since the additional risk requires a more advanced model of care coordination.

Moreover, there needs to be greater consistency in the quality criteria required, since providers are often confused by the nuances and differences between the criteria required

under different programs and providers desire to treat all their patients in the same manner.

5. *What financial arrangements would be most appropriate for ACO's assuming risk for Medicare and Medicaid expenditures?* Whatever payment arrangement is selected it must provide the greatest opportunity to use resources to support integrated care and remove artificial segmentation that fosters uncoordinated and inefficient care. While separate but coordinated shared savings arrangements might achieve this goal a unified shared savings arrangement is more likely to achieve this goal. Payments should be risk-adjusted to take into account the difficulties presented by the subgroups of the population served. In addition, as noted above, duplicative administrative and regulatory requirements should be avoided that increase administrative costs for those providing care to the population served.

Finally, as also noted in our general comments, we continue to wrestle with our desire to continue in the ACO program as it relates to the costs of implementation, which currently are in excess of the savings we have achieved. We will need to understand the total historical costs of the dual eligible beneficiaries for whom we are responsible, and the manner in which any benchmark will be established, before we are able to judge our desire to participate. We will also need to understand any benefit enhancements or standards that the State may impose on us before we can judge the financial consequences of participating in the initiative.

Other Comments

B. Integrating Accountability for Medicare Part D Expenditures

2. *Would ACO's be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefit s management companies?* There is a great opportunity to save dollars and improve care in Part D. Patients and doctors dislike restricting access to medication, but it is an area of great need of improvement in Medicare, where unnecessary branded drug use runs rampant by uneducated providers. The ACO would need to partner with a pharmacy benefit manager (PBM). To be successful we would need to be able to eliminate choice of drugs, with one or more of the following: (i), a tiered formulary with prior authorization requirements designed by a competent physician and pharmacy team; (ii) the ability to structure copays to direct members to lower cost drugs, and (iii) data feeds from the PBM or CMS to allow real time adjudication of claims/requests to fit the formulary. The tiered formulary would also need to be sufficiently flexible to avoid unforeseen expenditure acceleration. Finally, the financial incentives would need, at a minimum, to be sufficient to pay the

PBM. This is another area where complete beneficiary freedom of choice does not appear to be compatible with the goals of saving money for the program.

D. Other Approaches for Increasing Accountability

CMS seeks input on other potential accountable care models not specifically address in Approaches A through C.

In Michigan, the Governor has proposed a State Healthcare Innovation Plan (SHIP) that calls for something similar to a provider-led community ACO. This is a very exciting concept and would require close collaboration between CMS and a State. The current arrangement in Medicaid and CHIP is for the State to contract with multiple health plans, all of whom contract with the same providers to actually provide the service leaving providers to struggle with multiple administrative processes, reducing efficiency and increasing cost. Under this type of initiative the providers can lead the effort and have a single set of payment and administrative requirements reducing administrative costs and inefficiency and aligning incentives in a single way thereby increasing the opportunity for behavioral change on the part of providers.

If CMS constructed a carefully designed model of multiple service and payment reform initiatives within an ACO context it could have the potential to increase the opportunities for improved outcomes.

Thank you for the opportunity to submit these comments to the RFI. Again, we appreciate the learning opportunity we have had through our participation in the Pioneer ACO model and the willingness of CMS to work with us to achieve the overall goals of the program.

Michigan Pioneer ACO
Stuart Lockman, President

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. Second Request for Applications for the Pioneer ACO Model

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

Yes.

Why Organizations **Would Be Interested** in Applying to the Pioneer ACO Program

1) Existing Pioneers have had a very positive experience working with CMMI. CMMI has provided program participants with critical support and guidance through the early stages of the program and has been highly receptive to Pioneer feedback, fostering a trusting and candid partnership that allowed participants to navigate hurdles quickly and effectively.
2) There appears to be a new ground swell of political support behind ACO-like solutions, with proposed bicameral, bipartisan legislation. These announcements give potential participants greater confidence in the longevity of the model, allowing them to consider making longer term investments in this demonstration. Examples include:
    - Better Care Lower Cost Act which recommends that patients with multiple chronic illnesses be transitioned into ACO-like care coordination systems
    - SGR Repeal language which recommends incentives for physicians to participate in "Alternative Payment Models" including ACOs
3) The Pioneer ACO Model is Viewed as Superior to MSSP
    - There seems to be growing consensus among the "wait-and-see" providers, who chose to observe the early adopters in the MSSP and Pioneer programs before jumping in, that the Pioneer program offers a more progressive and flexible approach.
        - Superior prospective attribution method
        - Opportunity to access alternative payment arrangements
        - Opportunity to access Pioneer waivers
4) Many Other Specific Pioneer ACO Model Features are Viewed Favorably
    - CMMI Team Leadership. CMMI's leadership and staff are widely viewed by Pioneer ACOs as the most capable team in HHS. They are great ambassadors for CMS and have the requisite enthusiasm, patience, and endurance to drive this challenging demonstration.
    - Reporting. Although CMS has struggled to produce reports timely and with 100% accuracy, the reports and data files are, overall, very helpful and comprehensive sources of rich data, not previously available to Medicare physicians.
    - Open communications. The CMMI Pioneer ACO staff provides very thoughtful and timely responses to the ACO's questions. CMMI team members make themselves readily available to the Pioneer ACOs whenever necessary in spite of being short-staffed.

- Capped Medical Expense. This feature provides protection to the ACOs from excessive high cost beneficiaries, at no direct expense to the ACO.

5) Proliferation of Performance-Based Contracts is Slowly Changing Culture
   - The proliferation of commercial ACOs and Medicare ACOs is driving more physicians into performance based contracts in their traditionally fee-for-service lines of business.
   - There appears to be growing acknowledgement by physicians that volume based reimbursement is being replaced by value-based reimbursement.

Monarch HealthCare expects to see increased interest in the Pioneer ACO program from the following types of organizations:

1) Existing Pioneer ACOs

Monarch expects most existing Pioneers will recommit to "Pioneer 2.0" if CMS makes some evolutionary changes to the program's design. Organizations like Monarch are interested in testing and shaping design features that are important to the future of the program, such as:

- Transition to capitation and partial capitation with safeguards and protections
- Patient engagement and enhanced benefits
- Special population focus such as frail elderly, institutionalized, poly-chronic, etc.
- New methods for measuring performance using more timely metrics and/or relating directly to specific interventions
- Long-term sustainability and differentiation of the ACO, Medicare Advantage and traditional Medicare programs

a. **Hospital systems who are building an employed integrated ambulatory group or medical group foundation**

The Pioneer ACO Model is attractive to hospital systems developing their ambulatory care strategy because this represents an opportunity to attract and retain Medicare patients, who have historically been relatively provider/hospital agnostic.

2) Integrated Delivery Systems

The Pioneer ACO Model may be attractive to integrated delivery systems who (1) are philosophically aligned with the Triple Aim mission, (2) believe they are sophisticated enough to improve outcomes and have hospital alignment to lower inpatient costs for traditional Medicare populations, and who (3) have developed confidence that the program has matured and stabilized. Entrants may include:

3) Medicare Shared Savings Program Participants

The Pioneer ACO Model will be very attractive to MSSPs who feel they are prepared to take greater risk for this population and recognize opportunities for rapid cycle innovation in the Pioneer program, which are unavailable in the MSSP program (ie. 3 Day Inpatient Stay Rule Waiver, broader specialist attribution, etc.)

4) Employer Groups, Unions, and Community-Based Organizations

Monarch HealthCare believes there is interest from these types of organizations wishing to provide a lower cost, care coordination product to retirees at a price point between an HMO and a PPO product

Why Organizations **Would Not Be Interested** in Applying to the Pioneer ACO Program

1) **Inertia**
   - FFS still pays for volume, pays quickly, and guarantees to pay 100% of the Medicare Fee Schedule for allowable services.
   - There is currently no penalty for poor patient outcomes, and no guarantee of higher pay for ACO participation.
   - Independent physicians are entrepreneurs who've built a business with a known and reliable source of income and are reticent to put that in jeopardy. With no immediate penalties or rewards to prompt change, physicians are disinclined to take action.
   - ***CMS should test the impact of immediate physician participation incentives to encourage physicians to join ACOs***
2) **Cost and Risk with Uncertain ROI**
   - Insurance risk of the program may be seen as too large given the shared savings opportunity
   - Costs of operations and compliance may be seen as cost prohibitive given shared savings opportunity
   - Program continues to evolve, thus unable to clearly define its long term strategic direction and sustainability, including full or partial insurance risk features
   - Perceived inability to control medical costs:
     i. Open network and self-referral perceived as prohibitive to cost containment.
     ii. Perceived inability to impact acute admits due to lack of real-time notification
     iii. Inability to influence patients' care-seeking behavior via benefits and steerage
3) **Quality Measurement & Reporting**
   - ACO quality measures are different for ACO seniors than the already familiar Medicare Advantage Star Quality Measures for seniors
   - New measure sets require new EHR configurations, new practice workflows to collect data, new reporting processes, and new training to support all of these changes.
   - There is significant expense and time associated with this type of change at a time when reimbursement is declining and physician practices are tightening their belts.
   - The expense associated with data collection and reporting for physicians not on an EHR is prohibitive, and incentives to promote EHR implementation are not meaningful enough to motivate the late adopters.
   - ***CMS should align ACO quality measures for seniors with the Medicare Advantage Star Quality Bonus Program measures. There should be no reason to require physicians to implement two distinct quality improvement programs for their senior patients.***

4) **Complexity of Calculations**
   - We applaud CMS' attempt to avoid the use of HCC-based risk adjustment to develop a benchmark by using historical claims of the attributed population.
   - However, this method appears to omit some historical claims, and it may not be possible to recover all of those historical claims with 100% certainty
   - Those missing historical claims tend to be decedent claims for patients in their last year of life when claims costs are most volatile and impactful
   - In earnest, CMS has attempted to resolve this issue by "back casting" or estimating those missing historical claims
   - This exercise has convinced current participants that this method is fundamentally flawed, has grown far too complex, and is moving further away from a proven, accurate method for forecasting patient cost
   - The current benchmark calculation cannot be reconciled with actual claims data or reverse engineered by Pioneer organizations
   - An additional and significant disadvantage of this methodology is that Pioneers cannot calculate patient-level benchmarks, prohibiting us from setting benchmark targets for our individual patients and thus for our individual physicians, which prohibits us from reliably/credibly tying incentives to the medical cost performance of an individual physician – a fundamental component of performance-based contracts.
   - We find the current benchmark methodology to be a critical weakness in the program's design that will prove to be a key deterrent to program participation
   - ***CMS should replace the current benchmark calculation with a method that incorporates episodic care analysis as the foundation of risk adjustment, and avoids incentives for ACOs to invest in risk score inflation***

5) **Other Data Challenges**
   - The Pioneer ACO program must bolster confidence in the accuracy and timeliness of reporting, a current challenge which is widely perceived as prohibitive to ACO success.
   - ***CMS should seek additional support to produce and quality check critical data files and performance reports.***
   - ***CMS should make clear to potential entrants the changes the program has made to improve the transparency and simplicity of the model. It is imperative that CMS minimize methodology and calculation changes, once the new contract period begins. CMS must commit to potential participants that they will be insulated from any negative impacts resulting from methodology or calculation corrections that impact current or past performance years.***

6) **Weak Patient Engagement**
   - Patients currently have no incentive to support physicians and the ACO in improving health outcomes or reducing medical cost
   - ***CMS should offer patients enhanced benefits that reward quality- and cost-conscious healthcare choices***

- ***CMS should support Pioneers to promote the legitimacy of ACOs and help explain that the program does not place their existing Medicare benefits at risk***

7) Delayed Shared Savings Payments

- Shared Savings for PY1 were distributed to Pioneer ACO's 20 months after the first day of performance year 1, and more than 27 months after most participating physicians signed their contracts.
- As currently structured, the fastest a potential Pioneer participating physician can ever expect to collect shared savings will be no less than 24 months after the last date that the physician commits to participating in the ACO
- The key rate-limiting factors prohibiting prompt payment of shared savings are:
    i. Claims lag – *Implementing prospective payment/capitation would resolve this issue because performance-based payment could be distributed to physicians by the ACO throughout the year*
    ii. Delay in reconciling actual costs with the benchmark – *Implementing prospective payment/capitation would obviate the need to perform this retrospective calculation for the purposes of paying shared savings – physicians would already have been paid incentives throughout the year by the ACO.*

Ex) Hypothetical 2015 Performance Year Physician Experience:

- **June 30th, 2014** – Last day for physician to sign 2015 performance year contract – the required 30 days in advance of a July 30th, 2014 network submission deadline
- **January 1st, 2015** - Physician begins to see attributed patients and begins to perform work to achieve shared savings
- **April 30th to May 31st, 2015** - Claims are "complete" 4-5 months after year end
- **June 30th, 2016** - CMS distributes shared savings to Pioneer ACOs, two years after the last possible date for the physician to commit to the ACO

- This delayed incentive is unattractive and ineffective in persuading most physicians to leave the certainty and reliability of FFS payments
- ***CMS should implement prospective payment/capitation***

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

CMS should strive to attract a broader range of participants into the Pioneer program and allow them to assume an appropriate level of risk and reward. To accommodate organizations of varied experience and sophistication, CMS should offer multiple payment arrangements each with appropriate eligibility criteria. The number of participants should only be limited by the qualifying criteria, rather than by an arbitrary count of participants.

With that said, Monarch HealthCare believes CMMI is currently under-resourced to support the existing Pioneer program participants, so an expansion of Pioneer program participants will require a disproportionate expansion of the administration and support of the program. Additional support should be focused on data and reporting functions to improve timeliness and accuracy.

Also, by broadening criteria for participation, CMS should anticipate that the needs of the less sophisticated entrants will be greater than the needs of past program participants.

Advantages of Using Broader Criteria to Set Participant Limits

- Will result in a larger number of patients who will benefit from Pioneer services including quality improvement, care coordination, disease management, etc.
- Will result in larger number of participating physicians and expansion of performance-based contracts
- Will increase the volume of data submitted for quality reporting

Disadvantages of Using Broader Criteria to Set Participant Limits

- Increased complexity of administration for CMMI - By broadening and stratifying participant criteria, CMMI would have to manage a more diverse group of participants with a broader set of payment arrangements, adding to the complexity of administration
- An increase in the number of participants in the same markets may create silo'd communication and competitive behavior, inhibiting care coordination between organizations – CMMI may have to consider creating non-exclusivity requirements to encourage communication between all Medicare providers regardless of their primary ACO affiliation; Such non-exclusivity requirements already exist in the Medicare Advantage program to address this potential issue.
- Lack of standardization of ACO benefits and services across a broader set of participants may inhibit beneficiary engagement and understanding of the program's value

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

For the Pioneer ACO Model to become a viable alternative to Medicare fee-for-service, and to attract a critical mass of participants, the program must be attractive to three critical stakeholders, in this order:

1) The patient
2) The independent physician
3) The integrated delivery system

1) Pioneer ACO Model Success Hinges on Patient Demand

If patients ***choose*** this product, the rest of the delivery system will follow. The growth of Medicare Advantage enrollment demonstrates that patient behavior is economically rational. Over time they will compare products and choose the product of greater value. Medicare Advantage penetration has grown steadily over the past decade, with over 29% of eligible patients now enrolled. However the Medicare Trust Fund can't wait for Medicare Advantage to enroll the remaining 70% of patients, for two reasons:

- The Medicare Advantage market saturation point appears to be in the 60-70% penetration range, with only a handful of counties in the country reaching that level. Average penetration is just over 29%
- Increasing pressure on Medicare Advantage health plan economics is expected to result in benefit deterioration and enrollment stagnation

In order to transition the rest of the Medicare population into a system of coordinated care, patients must be given a third option that is of meaningfully greater value than original Medicare. When patients choose that product, providers will be compelled to participate in the program that their patients have chosen.

CMS must make the Pioneer ACO Model more attractive to patients by offering enhanced benefits, and CMS must then give patients the opportunity to opt-in.

2) Guaranteed Physician Incentives Will Accelerate Adoption

If patients do not find meaningfully differentiated value in this product and are not allowed to opt-in, then CMS will have to attract independent physicians and integrated delivery systems to participate without the help of patient demand. This will be a slower and more expensive path.

Volume based reimbursement is a powerful incentive, creating significant provider inertia. To prompt providers to experiment with a new payment model, the value proposition to change must exceed the value of remaining a fee-for-service physician. Fee-for-service inertia is particularly strong with independent physicians, whose compensation is 100% variable with claims submission. Shared savings are neither guaranteed, nor timely enough to overcome fee-for-service inertia for most independent physicians.

CMS must offer a guaranteed incentive to physicians who choose to participate in a Pioneer ACO Model to attract the physician and support them through the transitional period (3-5 years).

3) Hospital ACO Adoption Remains Challenging

In general, hospital incentives and ACO incentives are diametrically opposed. 67% of Monarch's Pioneer ACO medical cost was driven by hospital inpatient claims. Nationally, inpatient claims account for XX% of Medicare medical expense. And research indicates that up to 75% of hospital admissions are avoidable. By far, the greatest opportunity to reduce medical cost and improve patient outcomes is by preventing hospital admissions and readmissions.

Hospitals may participate in Medicare ACOs to capture the following moderately compelling opportunities:

- Collect shared savings to mitigate the greater losses associated with reduced hospitalizations
- Gain greater visibility into longitudinal patient care in order to repatriate patients
- Align physician incentives to retain planned admissions and to promote utilization of the hospital's outpatient services

For hospitals without an integrated ambulatory delivery system, there is limited value in ACO participation. For integrated delivery systems, an ACO represents an opportunity to mitigate losses on the inpatient side and attempt to control Medicare market share.

Additional Refinements to Engage Key Stakeholders:

In addition to offering benefit enhancements to patients, to improve engagement, Monarch recommends CMS offer the following program refinements:

- Protect participating ACO providers from SGR impact
- Offer a 3-5% fee schedule increase to participating ACO physicians for their first 3 years in the program or…
- Offer an annual update that exceeds the annual update for non-ACO providers (ie. 150%-200% of non-ACO physician's annual update)
- Increase shared savings percentages by at least 10% to providers and reduce CMS share to offset high administrative costs (provide risk/reward balance)

B. Population-Based Payments

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

The Perspective of the Independent Physician:

No. The ability to choose different FFS reduction amounts for Part A and Part B is not a factor for independent physicians like those in Monarch's ACO, when they consider participating in PBP. As it is currently structured, PBP is not attractive to independent, non-salaried physicians. We believe Monarch's view represents that of independent physicians across the country which account for 53% of the country's physicians.

Most of Monarch's participating ACO providers are not employed by the Pioneer organization. They are independent "contracted providers" who do not receive a salary from the Pioneer organization. They depend on the revenue that each Medicare allowable service generates to fund the ongoing operations of their independent practices. Participating in PBP requires that our independent physicians elect to absorb a discount to their usual Medicare reimbursement for ACO patients, with the hope of receiving more-than-offsetting shared savings at year's end. From the perspective of the contracted provider, any reduction to Part A or Part B reimbursement has a direct impact on cash flow without the guarantee of a corresponding and offsetting benefit.

A Pioneer ACO may be able to attract independent physicians to choose PBP by minimizing this burden on their contracted providers and selecting a very small reduction (eg. 3-5%). However this small sum is not enough to make meaningful investments in services to improve coordination of care. This solution holds no value for the Pioneer and yields little improvement in care coordination.

This is particularly true for Monarch's Pioneer ACO, which has pursued a narrow PCP-centric network strategy, in which all aligned providers account for less than 6% of total Part A and Part B claims. While a "temporary" 3-5% discount may be almost palatable to our physicians, the net PBP amount would be a fraction of a percent of total Part A and B claims value ("3-5% discount" x "6% of total PBP participant claims") – a number far too small to make any meaningful investments in care coordination activities.

A reduction of a larger amount (eg. 30%) would provide more resources to the Pioneer ACO to invest in care coordination however most independent physicians cannot afford to take a 30% pay cut. This solution is unattractive to the independent physician even with the promise of potentially greater returns, because those returns, paid long after the end of the performance year, don't help finance his/her day-to-day operations during the performance year.

Ultimately, a reduction of any amount simply results in delayed payments to contracted providers. That delay is more harmful to the operating cash flow of the business than any shared savings may be when paid retrospectively.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

Though Monarch is not interested in PBP as it is currently structured, we see no reason why this benefit should not be included on the list of PBP-participating Pioneer providers suppliers that would receive reduced payment. In general, Monarch believes that carve-outs of any type of healthcare service result in unnecessary fragmentation of the patient's care, and run counter to the care coordination objectives of the program. For those organizations participating in PBP, giving DME providers an incentive to reduce cost may be a valuable tool to encourage cost management of a historically abused benefit.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

Under Current PBP Definition

Pioneer ACOs should not be required to generate a specified level of savings in previous years to be eligible to elect to receive PBPs. The intended purpose of PBPs is to allow the Pioneer ACO to invest in activities that will create savings and are not otherwise reimbursed by Medicare. Pioneer ACO's must be permitted to participate in PBP and implement medical cost savings initiatives with those funds, however, CMS should require that Pioneers demonstrate adequate risk-based capital reserves to cover their downside financial risk.

Under Capitation

Monarch proposes that the definition of PBP be expanded to include capitation for all or part of the total cost of care for ACO beneficiaries. If PBPs are redefined as capitated prospective payments, Pioneer ACOs should not be required to generate a specified level of savings in previous years to be eligible to elect to receive PBPs in future years. Under this arrangement, by participating in PBP the Pioneer knowingly accepts full risk for some portion of medical expense, and has taken accountability for any potential losses. CMS should require that Pioneers demonstrate adequate risk-based capital reserves to cover their downside financial risk, rather than prohibit Pioneers from accepting downside risk, an arrangement which should result in better performance.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

For those who wish to continue to participate in PBP as it is currently defined, CMS must remove or significantly reduce the withhold amount, which is currently 3%. Regardless of payment arrangement, the maximum savings limits combined with the quality score performance coefficient, are an adequate incentive/penalty to drive ACO performance, deliver savings to the Medicare Trust Fund, and provide ACOs with a very narrow opportunity to make a profit.

For example, Monarch was the second highest performing Pioneer ACO in PY1 in terms of medical cost savings, with gross savings of about 12.2%. If we were to repeat that performance in PY3, and we also opted-in to PBP, assuming we achieve 100% quality score performance (unlikely), our net savings after withhold would be too small to cover administrative costs and pay our physicians a meaningful shared savings amount.

We expect no ACOs to achieve a quality score of 100%, so even if baselines are not significantly recalibrated down in PY4, the allowable net savings opportunity going forward will be smaller than the example scenario illustrated above. The 3% withhold will be even more damaging to the Pioneer ROI making PBP participation economically unattractive.

Section II: Evolution of the ACO Model

A. Transition to greater insurance risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

Yes.

Benefits & Rationale:

Capitation is Imperative to Engage Independent Physicians and Extend ACO Access to More Patients

It's imperative that CMS understand the importance of capitation to a Pioneer ACO which is comprised of mostly independent physicians who are not employed or salaried by the Pioneer ACO or a hospital system.

About 80% of Monarch's Pioneer ACO participating physicians are independent. The American Medical Association recently published a study indicating that more than 53% of all practicing physicians in the U.S. in 2012 remained independent – they fully or partially owned their practice. In order to make the Pioneer ACO Model attractive to more than half of all practicing physicians in the U.S., CMS must offer a payment arrangement that adequately incentivizes the independent physician to participate and to perform.

With no salary to fall back on, independent physicians are more dependent on fee-for-service income than their hospital-employed counterparts. Fee-for-service-dependent physicians are paid only when they are working and generating claims. If they take vacation or stop submitting claims, there is an immediate impact on their income and the operating cash flow of their practice.

In order for an independent physician to leave the certainty and predictability of fee-for-service payments, they must be absolutely certain that the alternative payment arrangement is at least as valuable and reliable.

Capitation provides the Pioneer ACO with the capital to quickly and adequately pay independent physicians, ending their dependence on claims submission for income, without disrupting their cash flow. This will eliminate a critical barrier to participation for 53% of all practicing physicians and to the patients who would be attributed to them.

Capitation Has Proven Successful in Making Physicians Directly Financially Accountable for Improving Patient Outcomes

The figure below illustrates Monarch's actual performance managing senior patients across a variety of payment arrangements. Capitation is extremely effective in aligning provider payments with improved outcomes. Monarch delivers best-in-class medical cost and quality results for our globally capitated senior population.

Comparison of Senior Population Outcomes in Orange County, CA, Under Different Risk Arrangements
Quality and Medical Cost Improve Dramatically as Physicians Become More Directly Financially Accountable for Outcomes

↑ Financial Accountability = ↑ Performance-Based Incentives = ↑ Patient Outcomes

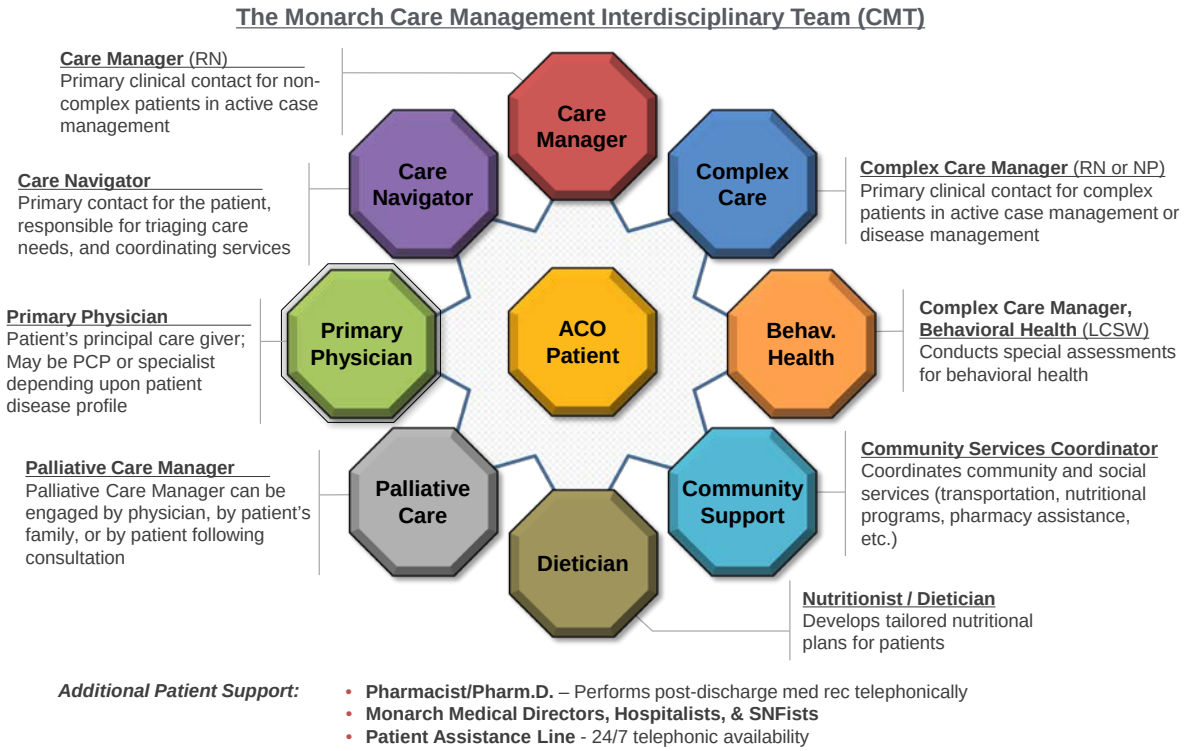
Line of Business	Monarch FFS	Monarch Pioneer ACO	Monarch Medicare Advantage	Monarch Medicare Advantage
Payment Methodology	Fee-For-Service	Shared Savings	Partial Capitation	Global Capitation
Performance Year	2011	2013 YTD	2013 FINAL	2013 FINAL
Population Description	Monarch Pioneer ACO Population, 1 Year Prior to Program Launch	Monarch Pioneer ACO Population, Performance Year 2	Monarch MA Patients Under Part B Capitation	Monarch MA Patients Under Global Capitation (Parts A & B)
Geography	Orange County	Orange County	Orange County	Orange County
Payment Arrangement				
ACO Physician Payment as a % of the Medicare Fee Schedule	100%	111%	140-150%	140-160%
Payment Lag	95% of claims w/in 30 days	95% of claims w/in 30 days; 11% bonus paid from shared savings, 7 months after yearend	Capitated rate paid prospectively each month with portion contingent upon recent performance	Capitated rate paid prospectively each month with portion contingent upon recent performance
Performance Metrics				
Hospital Bed Days/1000	1408	1143	1089	**918**
Hospital Admissions/1000	282	232	232	**201**
Hospital Readmission Rate	17.5%	15.7%	15.8%	**12.6%**
Skilled Nursing Days/1000	4225	3020	1284	**1085**
Skilled Nursing Admissions/1000	136	118	84	**69**
SNF Readmission Rate	16.6%	14.0%	14.5%	**11.7%**

Capitation funds physician incentives that produce dramatic improvements in patient outcomes and cost savings

Capitation Provides the Pioneer ACO With Funds to Make Discretionary Investments in Quality Improvement and Cost Prevention

A key contributing factor to the results described above in Monarch's capitated arrangements, is our ability to offer non-covered services to beneficiaries when they need them. Those services may include coordinating a patient's care after a hospital discharge, non-emergent medical transportation, home visiting physician visits, telephonic medication reconciliation, disease management support, and other services that may not be covered by Medicare. Capitation offers the appropriate funding and spending discretion to allow Monarch's clinical team to provide our patients with the appropriate services at the appropriate time.

Below is an illustration of the Monarch Care Management Interdisciplinary Team. Each Monarch patient requiring care management services is supported by an interdisciplinary team that is tailored to the patient's needs. This clinical team assesses each patient's needs and has the clinical expertise and budgetary discretion to support the patient however necessary.



Capitation Will Create Long Term Administrative Efficiencies for Medicare

The organization of physicians into Pioneer ACOs will consolidate payee relationships dramatically for CMS. Ultimately the delegation of administrative functions to Pioneer ACOs, including claims adjudication, customer service, appeals and grievances, physician credentialing, etc., will drive significant administrative efficiencies for CMS.

Capitation Directly Supports Sustainable Growth and Long Term Solvency for the Medicare Trust Fund

A market-adjusted medical cost budget guarantees a sustainable growth rate and long term visibility into Medicare medical spending.

Capitation Changes the Culture of Health Care Delivery

By definition, capitation is a budget – a finite limit on spending, that can be easily communicated to and understood by providers. Awareness of and accountability for spending limits will catalyze a shift in the culture of care for traditional Medicare beneficiaries. Practitioners will be forced to ask: "How do I improve this patient's health, or stability with scarce resources? Which services have the highest efficacy at the lowest cost?"

Capitation of Pioneer ACOs Obviates the Need for a Health Plan Intermediary and Avoids Those Administrative Costs that Currently Burden the Medicare Advantage Value Chain

Monarch HealthCare is the largest Independent Physician Association in Orange County. We care for over 180,000 HMO patients, 32,000 of which are Medicare Advantage patients. Monarch accepts global capitation for about half of our Medicare Advantage patients and we accept Part B (professional) capitation for the other half of our Medicare Advantage patients. We expect to accept global capitation for 100% of our Medicare Advantage patients by 2016.

In Monarch's global capitation arrangements we receive a prospective, per member per month payment from our Medicare Advantage Health Plan partners, typically 84-87% of the benchmark. We must use those funds to cover all Part A and Part B claims cost as well as most of the core administrative functions.

The only administrative functions that Monarch does not perform in our Medicare Advantage line of business are benefit design and sales. Monarch effectively accepts global capitation for only 84-87% of the Medicare Advantage benchmark. We believe we can deliver the same efficiencies to CMS as a globally capitated Pioneer ACO.

Risks to the Medicare Program

There are two primary risks to offering capitation that Pioneer ACOs must be equipped to address:

1) Accountability for down-side risk if medical costs exceed the capitation rate
2) Assurances that a capitated medical cost budget will not result in limiting patient choice

CMS must ensure capitation be made available only to those organizations that meet the following criteria:

- Ability to demonstrate experience and success with capitation for senior populations
- Ability to demonstrate the requisite IT and clinical infrastructure to support this payment arrangement
- Ability to demonstrate that this payment arrangement will not infringe upon beneficiary protections
- Ability to demonstrate that the organization has adequate risk-based capital reserves to cover losses
- Ability to furnish the applicable licensure allowing the organization to accept insurance risk

Risk Considerations for the Medicare Program

There are three primary risks to offering capitation that CMS must be prepared to address:

1) Pioneer ACOs must be prepared to take accountability for down-side risk if medical costs exceed the capitation rate
2) Assurances that a capitated medical cost budget will not result in limiting patient choice
3) Process for setting capitation rates must be fair, consistent and transparent

To address these risks, CMS must ensure capitation be made available only to those organizations that meet the following criteria:

- Ability to demonstrate experience and success with capitation for senior populations

- Ability to demonstrate the requisite IT and clinical infrastructure to support this payment arrangement
- Ability to demonstrate that this payment arrangement will not infringe upon beneficiary protections
- Ability to demonstrate that the organization has adequate risk-based capital reserves to cover losses
- Ability to furnish the applicable licensure allowing the organization to accept insurance risk

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

ACOs at full insurance risk should be responsible for Part A, Part B, and Part D. CMS should also offer "swim lanes" to accommodate both ACOs who wish to take full insurance risk and those who wish to take partial risk. CMS should provide just a few swim lanes to choose from to limit administrative complexity..

ACOs should not be accountable for Medicaid or Medicare-Medicaid beneficiaries. The needs of those patient populations are highly complex. Monarch believes that these patients require a care coordination program that can provide more structured and directive care. These patients are least capable of navigating the healthcare system independently and require more intensive care management than ACOs are currently capable of providing.

3. Are there services that should be carved out of ACO capitation? Why?

No. The patients that are most in need of care coordination support typically have a constellation of issues that are interconnected. By carving out services, CMMI risks fragmenting the patients care. Monarch believes that carving services out of ACO capitation is counter to the objectives of the program to provide comprehensive coordinated care to our patients, particularly to those patients with complex health issues. To that end, Monarch strongly encourages CMS to "carve-in" behavioral health and to share a broader set of behavioral health claims data with Pioneer ACOs, which may shape a critical component of the patient's care plan.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

No contract should be "required" between the ACO and non-ACO providers. Pioneer ACOs should be allowed to negotiate contracts with non-ACO providers as well.

The quality and cost performance objectives that ACOs are incentivized by will naturally drive ACOs to arrange contracts with those non-ACO providers who provide efficient, high quality care management. Conversely, ACOs will also seek out low performing non-ACO providers who provider a significant amount of care to ACO beneficiaries, in order to striker contracts designed to improve their performance.

Over time ACOs will strike performance-based contracts with the largest possible network of high quality physicians who will collectively guide patients toward other high quality, low cost healthcare services without limiting patient choice.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would not be appropriate for ACOs assuming full insurance risk?

Monarch suggests that CMS base ACO compliance guidance on Medicare Advantage compliance guidelines, omitting those requirements that are not applicable to the Pioneer ACO program. We recommend that CMS consider the following guidance for each key regulation:

Compliance Requirements		Applicable to Advanced ACO	Currently in place at Monarch for MA Patients	Currently Required of FFS Physicians	Currently Required of Pioneer ACOs	Currently Required of MSSP ACOs	Currently Required of Medicare Advantage Provider	Enhancements to Compliance Oversight, Not Available in Existing Medicare FFS System	Impact on FFS Providers	Implementation Time Required (for an organization with no existing Compliance Program)	Approximate Investment Required
Element I	**Written Policies, Procedures and Standards of Conduct**	✓	✓	✗	**Limited**	**Limited**	✓	Requires Standards of Conduct which describe the organization's expectations that all employees conduct themselves in an ethical manner; that issues of noncompliance and potential FWA are reported through appropriate mechanisms; and that reported issues will be addressed and corrected. Establishes standards for compliance policies which address issues such as the organizations' compliance reporting structure, compliance and FWA training requirements, the operation of the hotline or other reporting mechanisms, and how suspected, detected or reported compliance and potential FWA issues are investigated and addressed and remediated.	More effecitive FWA Communication & Oversight: Physicians will receive more frequent, more transparent, and often tailored communications around FWA compliance. Results in FWA and compliance policy that addresses local care delivery and billing patterns, not easily identifiable by CMS in administrative data.	2-4 Months	<$15K to develop <$1 PBPY to maintain Primarily driven by allocation of existing FTEs to document and publish processes uniformly
Element II	**Compliance Officer, Compliance Committee and High Level Oversight**	✓	✓	✗	✓	✓	✓	Requires dedicated compliance staff at the Medical Group level overseeing beneficiary protections and facilitating patient communication locally.	Same as above.	1-3 Months	<$25K - $150K Range driven by decision to allocate existing FTEs to oversee compliance program vs. adding new Compliance Officer
Element III	**Effective Training and Education**	✓	✓	✗	✓	✓	✓	Requires the establishment and implementation of effective general compliance and FWA training and education for the Pioneer ACO governing body and employees or contractors of the Pioneer ACO and Pioneer Providers/Suppliers. Training topics include: • Laws and regulations related to ACO FWA; • Obligations to have appropriate policies and procedures to address FWA; • Processes to report suspected FWA to the organization; • Protections for individuals who report suspected FWA; and • Types of FWA that can occur in various settings in	Physicians will receive more targeted, comprehensive training around compliance with FWA requirements and beneficiary protections.	3-4 Months (in-house development & implementation) 1-2 Months (outsourced development & implementation)	<$10K to develop <$1 PBPY to maintain Cost of developing training and education content should be less than $10K. Cost of deliving education and training will vary by size of the organization.
Element IV	**Effective Lines of Communication**	✓	✓	✗	**Limited**	**Limited**	✓	Establishes standards for establishing systems to receive record, respond to and track compliance questions or reports of suspected or detected noncompliance or potential FWA from employees or contractors of the Pioneer ACO, Pioneer Providers/Suppliers, and other individuals or entities performing functions or services related to Pioneer	Provides a process to flag potentially wasteful or abusive behaviors to allow ACO to provide prompt notification to CMS of FWA violations and to re-educate and retrain physicians.	2-3 Months	~$6 PBPY Requires hiring and training of patient service team. Varies by size of population.
Element V	**Well-Publicized Disciplinary Standards**	✓	✓	✗	✗	✗	✓	No intermerdiary currently exists to ensure FFS patient protections are being enforced and that standards are reinforced with Medicare certified providers.	Physicians will have better access to compliance policies and standards through ACO systems and communications.	2-4 Months	Minimal incremental cost to communicate program requirements and include in physician contracts.
Element VI	**Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks**	✓	✓	✗	✗	✗	✓	Establishes standards to implementing effective system for risk assessments, monitoring and auditing work plans, tracking an documenting compliance, OIG/GSA exclusion screening and the use of data analysis for fraud, waste and abuse prevention and detection.	Provides support to physicians in identifying poor billing practices, fee schedule changes, and regulatory changes that may directly impact them and potentially place them in violation of compliance requirements.	4-6 Months	<15K to develop monitoring tools/reports ~$1-2 PBPY for ongoing intenal monitoring, auditing, and quality assurance
Element VII	**Procedures and System for Prompt Response to Compliance Issues**	✓	✓	✗	✓	✓	✓	Compliance issue response time performance should exceed existing compliane issue response time from CMS.	Provides a local channel of communication for patients that Medicare physicians generally do not have the capacity or expertise to	3-4 Months	Minimal incremental cost to develop phone line, and compliance response process to be facilitated by the compliance

Proprietary and Confidential

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

Monarch HealthCare is already licensed in California to accept full insurance risk for our Medicare Advantage global capitation contracts, via our "Limited Knox Keene License." We have already begun the process of extending our Limited Knox Keene License to cover the Pioneer ACO in preparation for taking greater insurance risk for our ACO beneficiaries. The key remaining requirement for Monarch HealthCare will be to demonstrate adequate risk-based capital reserves for the at-risk population. Monarch HealthCare has the capital and experience to prepare ourselves to accept full insurance risk for ACO beneficiaries, however other organizations may encounter a number of hurdles:

- Organizations that have no existing state licensure to accept insurance risk may require a lengthy application and approval process.
- Organizations unfamiliar with state licensure requirements may find they are ill-prepared to begin to manage the exhaustive regulatory and compliance requirements.
- Organizations may not be able to reserve the risk-based capital required by their state licensure.

Monarch does not believe that California-based ACOs would require further FWA waivers than are already available to Pioneer ACOs and/or to Medicare Advantage plans operating in the state.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

Monarch HealthCare currently supports every key administrative function necessary to operate a Medicare Advantage health plan except for benefit design and sales, which are not applicable in an ACO where the FFS benefit is static and no enrollment process is available.

Other organizations not experienced managing full delegation of administrative activities for Medicare Advantage populations, will have to contract with a third party administrator or develop at least the following major functions:

- Medical Economics/Actuarial Support/Analytics
- Claims administration
- Denials/Appeals/Grievances
- Customer Service/Call Center
- Enrollment/Reconciliation
- Marketing
- Regulatory & Compliance Management / Legal

This list assumes that by accepting prospective payment/capitation, the Pioneer ACO would have to be responsible for adjudicating claims according to the terms of the performance-based contracts that they've struck with participating and non-participating providers. Monarch recommends that all Medicare beneficiary claims continue to be submitted by providers to the existing Medicare Approved Contractors that they send Medicare claims to today. Currently those contractors verify patient eligibility and adjudicate those claims on behalf of CMS. Similarly, these MAC's would verify patient eligibility, identify ACO patient claims, and instead of adjudicating the claim, the MAC would forward those claims to the

Pioneer ACO for adjudication according to the terms of the physician's performance-based contract with the Pioneer ACO.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

The basis of capitation rates should be a combination of the prevailing FFS cost, and adjusted average per capita cost (AAPCC) of an unattributed local/regional reference population with similar disease prevalence/acuity as the ACO population.

The basis of capitation rate trends should be the local trend, not a national reference population trend which inappropriately weights a Pioneer ACO's capitation rate trend with the irrelevant trends of entirely different market with incomparable economics. This will lead to natural advantages for some and disadvantages for others such that Pioneer ACOs will either opt-in or opt-out based on the arbitrage opportunity, rather than their ability to actually bend the cost curve in their local market.

A locally-based capitation rate also appropriately takes into consideration unique local policy changes (ie. California's rural hospital rate increases) that a national reference population trend does not take into consideration, unfairly penalizing the Pioneer ACO and understating the organization's true impact on local trend.

9. What are the advantages or disadvantages of different strategies for risk-adjustment?

Monarch recommends that CMS avoid the HCC-based risk adjustment methodology used in Medicare Advantage which will invite significant redirection of resources to optimization of diagnosis coding at the expense of quality improvement activities. However, Monarch strongly encourages CMS to consider other approaches that adjust for patient acuity and predicted utilization. CMS should not rely solely on demographic adjustment. This will inevitably lead to patient avoidance or patient dumping, and estrangement of the sickest population most in need of Pioneer ACO services.

Monarch recommends risk adjustment methodologies that are based on an underlying episode of care framework as the core risk adjustment methodology. Whether used prospectively to identify individuals for medical management interventions, or retrospectively to adjust for risk differences in measurement, the linkage between risk and episodes removes some of the challenges associated with the HCC methodology and creates a stronger linkage between performance improvement against risk adjusted cost targets, with the ability to identify what underlying components changed in order to meet the financial objectives.

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

CMS should offer benefit enhancements designed to encourage patients to choose higher quality, lower cost healthcare services. The benefit enhancement must provide an immediate

and material reward for such patient choices, and the value must be clearly identifiable before the patient is at the point of care such that the patient is able to "shop" for this enhanced benefit.

- Reduction in beneficiary cost share amounts when beneficiaries receive services at the ACO's preferred providers
- Reduction in beneficiary cost share amounts when beneficiaries enroll in care management programs
- Elimination or reduction in beneficiary cost share for medications needed to treat chronic diseases

Lower costs would result in improved patient compliance and drug adherence, and more care would be furnished by the highest quality physicians resulting in improved outcomes. Example enhancements include:

- Recommended Part A benefit enhancement: 10-15% coinsurance instead of 20%
- Recommended Part B benefit enhancement: $0 copay for primary care; $10 copay for participating specialists
- Recommended Part D benefit enhancement: $0 copay for generics and critical chronic care drugs

Monarch strongly recommends that any benefit enhancements be made universally across all Pioneer ACOs such that this enhanced benefit becomes familiar to and easily understood by Medicare beneficiaries across the country.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

- Ability to forecast and manage risk
- Ability to identify downstream providers capable of accepting risk, and willingness to cover downstream risk
- Ability to manage appeals and grievances and member services appropriately and timely
- Development of Infrastructure to manage risk including medical management, financial and actuarial, data management, reserves and reinsurance
- Ability to secure licensure to accept and manage risk and comply with state and federal requirements

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

CMS should require the distribution of patient educational materials, disclaimers about choice, access to a Medicare hotline to report benefit infringement and explanation of the appeals and grievances process.

Patient avoidance can best be mitigated by developing capitation rates that take into consideration that is risk-adjusted to reflect the acuity of the attributed patient population. A

well-designed program and capitation methodology should incentivize Pioneer ACOs to seek out the sickest patients most in need of care management support.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

Yes.

Beneficiaries should be allowed to elect alignment to a Pioneer ACO. Voluntary alignment should be expected to produce the following benefits for the Pioneer ACO program.

- Promotes patient stickiness from year to year, potentially reducing churn
- Indicates the patient's familiarity with and awareness of the ACO and should significantly improve their engagement in the ACO's programs
- Choice will lead to patient demand for ACO services, which will attract additional care providers to participate in the program
- Will increase total alignment, promoting awareness, visibility and economic stability for the program

Potential disadvantages associated with voluntary alignment may include:

- Potential marketing tactics that might be unwanted, unlawful or outside of CMS policy for marketing to beneficiaries
- Beneficiary may want to be aligned but do not meet eligibility criteria

B. Integrating accountability for Medicare Part D Expenditures

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

Monarch is actively engaged in a shared savings arrangement with one such Part D sponsor to better integrate management of our ACO patients' prescription drug benefit with their medical benefits, promote patient adherence, and reduce cost. We have found no barriers to the success or potential of that partnership thus far.

Part D sponsors are prohibited from offering services to a subset of their enrollees. It's our understanding that benefits (including ACO care management services) must be marketed and made equally accessible to the Part D sponsor's entire enrolled population, which may cover a region far larger than the ACO's footprint and would very likely not perfectly overlap with the ACO's attribution. CMS should allow Part D sponsors to market ACO services and support brand awareness with just those of their Part D plan enrollees who are in the ACO.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

Yes.

Monarch is considering partnering with a PBM to offer a branded ACO Part D product however, Monarch's target market is smaller than the Part D region that we're in. CMS should allow ACOs to offer Part D products exclusively to its ACO beneficiaries, even if that geography and population are a small subset of the eligible population in the Part D region.

We agree that ACOs should be licenced under state law as a risk bearing entity if the ACO chooses to become a risk-bearing Part D Sponsor.

We believe that ACOs should be allowed to pursue this option through the Part D bidding process if they choose but agree that CMS should develop a unified expenditure target for Parts A, B, and D with a common risk adjustment method to support coordination of these benefits and to simplify administration.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

No.

Monarch estimates that we receive between 30% and 50% of total Part D claims data for our ACO beneficiaries. In order for a Pioneer ACO to accept full risk for Part D expenditures it is imperative that we receive 100% of Part D claims for all beneficiaries with creditable prescription drug coverage. Monarch is in the process of purchasing data from third party vendors to collect a more complete set of Part D data for our ACO beneficiaries, however we will never have 100% of the data. It's unlikely that we'll be able to take Part D risk for beneficiaries who are not already in a PDP.

For those on a PDP, the Part D Sponsor is already at risk for outcomes and cost savings. For this reason we recommend CMS encourage Pioneer ACOs to either offer their own Part D plan to beneficiaries or partner with existing Part D sponsors to manage those patients who overlap with the Part D plan and the ACO.

C. Integrating accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

CMS should cautiously test the utility of the ACO model in caring for dually eligible beneficiaries. These patients tend to be more complex than the typical Medicare beneficiary. Monarch believes that these patients require more structure and a more prescriptive approach to care coordination than what is currently possible in the Pioneer ACO model. We encourage CMS to experiment with coordinating the Medicare and Medicaid benefit under the ACO model but without exposing participants to downside risk and potentially only in

states that are willing to collaborate to support experimenting with the model for dually eligible patients.

Monarch does not believe the current ACO structure and open network model will be an effective system for improving outcomes and reducing cost for the Medicaid population (non-Medicare eligible).

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

In this dual ACO demonstration, ACOs should be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically to promote continuity of care.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

From a Medicaid perspective, States could potentially play a role in model design, with strong focus on aligning objectives and incentives; IT infrastructure and data analytics. However, these for States to meaningful contribute in these areas then additional funds would need to be provided to the States since many states do not have additional capacity to design and administer ACO based programming. Examples, some States have been able to support ACO activity State Innovation Awards from CMMI, while other States like Minnesota and Iowa have ACO activity as a result of state legislation, much of which is unfunded, requiring the Medicaid program to redirect existing resources. Thus, CMS might consider supporting Medicaid collaboration on ACOs by extending enhanced federally matched funds for IT infrastructure. The business functionality needed by a state's Medicaid Management Information Systems (MMIS) to support ACO growth and effectiveness could be funded at existing enhanced match rates, with CMS effectively providing 90% of the dollars needed by states to develop the IT infrastructure needed to support proliferation of effective ACOs through a centralized data analytics "utility". Business functionality needed to support ACOs should be consistent with CMS's Medicaid Information Technology Architecture (MITA) vision for MMIS maturation – using the MMIS to support increasing Medicaid business functionality.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

The ability of an ACO to obtain and work with Medicaid administrative data rests on both the State's MMIS and/or the quality and timeliness of encounters from Medicaid Managed Care Organizations (MCOs) contracted to arrange clinical service delivery for Medicaid enrollees. Encounter data is notoriously poor quality, additionally; many state Medicaid agencies struggle to obtain Medicare data for use in understanding population risks and coordinating

the care of people dually eligible for Medicaid and Medicare. Without significant regulatory changes enabling improved access to, and use of, Medicare data for state Medicaid programs, and improved encounter data quality, ACOs that attempt to serve Medicaid recipients and dually eligible patients will be forced to struggle with data that is old, incomplete and unreliable for purposes of timely care coordination and quality improvement.

5. **What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?**

Standardizing and aligning quality metrics, contracting simplification, data and claims definitions, data privacy common framework and performance models among payers clearly affords ACOs the opportunity to participate in ACOs by reducing the burden of these similar but not quite duplicate requirements.

Because Medicaid and Medicare pay for different components of care for people who are dually eligible, determining a coordinated or unified shared savings model is essential. Given State to State differences between Medicaid benefit sets for those who are dually eligible, ACO participation is more likely possible in a unified model, especially if there is simplification concerning the complexities of total cost of care for people in waiver programs accessing a wide variety of home and community based services.

ACOs may have reservations about taking accountability for people in long term care settings where most of the services accessed are not provided by integrated delivery systems, and therefore outside any reasonable control in terms of price and quality. States are eager to explore mechanisms that manage long term care costs but until there is agreement about who keeps savings for specific service cost reductions between Medicaid and Medicare, including those who are dually eligible is likely to be unattractive to ACOs.

D. Other Approaches for Increasing Accountability

1. **A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?**

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

E. Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

CMS can contribute to this endeavor by

- Ensuring success of the government ACO programs (i.e., Pioneer and Medicare Shared Savings Program).
- Continued collaboration with other agencies and States to remove barriers and increase operational efficiencies to fuel ACO membership growth opportunities involving dual-eligibles, Medicaid, and exchanges.
- Collaborate with stakeholders to standardize quality measures and comparative data for scoring.
- Promote multi-payer contracts and standardized templates for contracting.
- Provide additional incentives (e.g., shared saving percentage increase) to ACOs that are accountable for a substantial portion of a community's overall population.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

- Develop, update and maintain a single set of risk adjusted quality measures and reporting methods applicable to all patient segments to be adopted by all payers
- Ensure that reporting and audit requirements are identical across all common quality measures
- CMS should lead the effort and collaborate with industry to eliminate the burden of multiple sets of quality measures
- Recommend an independent, respected organization be responsible for publishing and testing national quality measures and methods
- Leverage prior work of Integrated Healthcare Association in CA and national organizations such as NCQA and NQF

Montefiore
THE UNIVERSITY HOSPITAL FOR
ALBERT EINSTEIN COLLEGE OF MEDICINE

February 28, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: Center for Medicare and Medicaid Innovation Request for Information: Evolution of ACO Initiatives at CMS

Dear Ms. Tavenner:

On behalf of Montefiore Medical Center, I am pleased to provide input to the Centers for Medicare and Medicaid Innovation (CMMI) on next steps in the Pioneer ACO program. As the operator of New York's only Pioneer ACO, we have observed first-hand the coordination benefits the demonstration has offered to beneficiaries and providers alike. For Montefiore, the Pioneer ACO program has represented another evolution of its longstanding commitment to population-health initiatives that promote continuity of care across healthcare settings for hundreds of thousands of beneficiaries in the Bronx and lower Westchester.

We believe that the Pioneer ACO program is a vital tool for stimulating improved care coordination for Medicare FFS beneficiaries, too many of whom experience fragmented services. To that end, we emphatically recommend that the demonstration program continue and, ideally, become a permanent fixture of the Medicare program. Even so, there are steps that would push the model to the next level of innovation. We submit for consideration recommendations in three main areas: 1) expanding reach and community impacts; 2) improving long-term financial feasibility and; 3) supporting comprehensive care management.

1) Expanding Reach and Community Impact

Hybrid Attribution-Enrollment Model

We believe that ACOs would benefit from a hybrid attribution-enrollment model. Under such an approach, ACOs would receive annual attribution prior to the start of the performance year, as they do today. However, throughout the term of a performance year, ACOs would also be permitted and encouraged to engage with new unaligned FFS populations to explain the benefits of the program. If interested, beneficiaries would be allowed to voluntarily opt into the ACO, formally registering their interest with CMS.

To support more patient engagement and awareness of ACO models, CMS might empower institutions like insurance navigators, State Health Insurance Assistance Programs (SHIPs), and Area

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Administrations on Aging to help inform beneficiaries about the ACO model and delineate the benefits and features of local ACOs.

When beneficiaries opt-in, they could receive the benefits of any ACO care coordination programs immediately, although would not be incorporated into the financial benchmark calculation until the start of the following performance year so as not to disrupt financial expectations. To support care coordination in the year prior to their inclusion, we would request claims information on these beneficiaries from CMS at pre-determined intervals.

Our rationale for enabling a continuous opt-in process in addition to an attribution model, is that it allows ACOs to more rapidly scale and also be responsive to beneficiaries who may learn of the ACO and want to join. Additionally, in many cases, it takes quite a bit of time for clinical interventions and care coordination programs to take hold, therefore the sooner ACOs can engage with beneficiaries, the better.

Despite this recommendation, we do strongly support the attribution approach as the fundamental strategy for linking beneficiaries to ACOs, as opposed to a purely opt-in process. Notwithstanding the beneficiaries described above, the Medicare FFS population is generally one that has explicitly chosen a non-enrollment model and we believe that choice should be honored. Further, if the attribution algorithm is calibrated correctly, it should represent true connections between patients and providers and therefore obviate the need for a purely opt-in/enrollment model.

There could also arguably be improvements made to the attribution process to strengthen its ability to represent connections between beneficiaries and providers. For example, our ACO would benefit if CMMI could indicated which primary care providers or primary care specialists to whom attributed beneficiaries are tied.

Community Reinvestment

Accountable care models have the opportunity not simply to transform models of care for attributed beneficiaries, but to stimulate a culture of accountability that will impact larger populations of beneficiaries and providers. To facilitate broader public health-oriented initiatives targeted to communities that surround ACOs, we recommend that ACOs be required to devote a portion of any savings received into community reinvestment efforts. Our ACO would make such a commitment if CMS was willing to match ACO-driven contributions to the reinvestment fund. This fund, strengthened by the provider-federal partnership, could support community-driven public health objectives and also serve to educate the community at large about accountable care strategies.

2) Improving long-term financial feasibility

Refining Pre-Payment Structure

Outside of the Pioneer ACO context, Montefiore manages 200,000 beneficiaries through a mix of shared savings and global risk arrangements with Medicare, Medicaid, and commercial payers. It is our experience that global risk payment structures that provide prepayments to our delivery system enable creative investment in resources to promote improved care. Such structures truly move delivery systems away from volume-driven FFS reimbursement.

The population-based payment (PBP) option within the Pioneer ACO structure could provide this type of flexibility, but modifications are needed to improve operational feasibility. Specifically, we would request that participating providers not be required to submit two claims—one to CMS and one to the

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ACO—in order to receive payment. This feature is administratively burdensome and could disincentivize provider participation.

In the current PBP structure, it is also conceivable that the ACO may pay providers for services rendered to individuals deemed ineligible for the ACO many months later. This circumstance means that the ACO must theoretically recoup such payments at a later time, generating confusion and propensity for error. More timely data on enrollment changes would greatly simplify back-end financial reconciliations.

With these types of changes, we believe the population based payment option could in fact deliver the greater insurance risk that CMMI outlined in the RFI submission. This approach maximizes the opportunity for innovative payment approaches like bundled payments, or other modifications to the fee schedule and also provides more license to pursue impactful services that may not otherwise be reimburseable under Medicare FFS, such as telemedicine services delivered in an urban environment.

Infrastructure Investment Support

One significant challenge that ACOs face is that they must bear tremendous up-front investment costs to execute the model that may or may not be recouped some 18 months later, when shared savings are distributed. Even a system like ours, with our years of experience executing risk arrangements, requires infrastructure support. To that end, we suggest that CMMI make anticipated savings available to ACOs earlier on in the process. Specifically, CMMI might consider enabling ACOs to access payment after the first 6 months of a given performance year; this payment could be pegged to 80% of projected savings, distributed quarterly, and reconciled at the end of the performance year.

An alternative could be to apportion a small amount of shared savings retained by CMS toward a competitive grant fund that ACOs could apply to for the purpose of executing novel infrastructure improvement projects. Finally, we would add that a workable prepayment structure of the type described in the preceding section does not entirely address this issue because prepayments will be devoted to claims payment and establishing a claims payment infrastructure requires resource investment.

Promoting Sustainability in Benchmarks

We echo a concern articulated at the January 2013 MedPAC session on Medicare ACO Policy Options that constant improvement over an ACO's own benchmark is not sustainable. We believe that the current strategy to rebase the entire benchmark after the third year does not allow sufficient transition time to new financial parameters. We would recommend an alternative, graduated approach tied to quality performance. Entities that perform at a certain level on quality metrics would not have benchmarks rebased, those that perform a tier below would have their benchmarks partially rebased, and so on.

This strategy both allows for a smoother economic transition and further incentivizes the changes needed to achieve improved quality performance. In addition to graduating the rebasing timeline, we also want to note that a certain point, systems will achieve all of the efficiencies and savings they can reasonably attain. At that point, in order for ACOs to continue, CMS will need to move away from a shared savings approach to a benchmark that builds in a reasonable provider margin. Absent this pathway, ACOs will need to eventually leave the program, as shared savings in perpetuity are not achievable, and newer ACOs may be dissuaded from participating.

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Montefiore also strongly believes that CMS should continue to include IME and DSH in Pioneer benchmark calculations. These programs play a critical role in supporting services for low-income, underserved and underinsured populations. Generating efficiencies in an academic medical center environment is challenging given the fixed costs of our teaching and community-based missions. Continuing to include IME and DSH in the benchmark recognizes this added challenge and enables academic medical centers to access the full amount of savings they generate.

3) Supporting more comprehensive care management

Aligning Medicare, Medicaid, and Other Payers

In the first few years of operations, the Montefiore ACO has managed between 8-9,000 dually eligible individuals, accounting for about a third of our total ACO population. In many cases, these individuals face substantial clinical, financial, and social challenges that require intensive case management and disease management programs. These are single individuals, yet so often are enrolled in multiple and at times overlapping programs (e.g. ACOs and Health Homes), while navigating complex rules across the Medicare and Medicaid programs.

We are very supportive of the concept of incorporating Medicaid financial and clinical accountability into the Pioneer ACO model, so much so that the Montefiore ACO is in the midst of trying to develop such a pilot program for our Pioneer duals population with CMMI and New York policymakers. This type of integrated ACO would ensure better coordination of care for beneficiaries and potentially reduce confusion and barriers that may result from enrollment in the two insurance programs.

We would also potentially be interested in a multi-payer ACO or a model where a single ACO assumed responsibility for a broader range of beneficiaries in a given catchment area, much like the Medicaid Health Home model. While we favor the concept of pushing out the benefits of care coordination to a broader audience, we also believe that utilization patterns should guide the level of financial incentives. In other words, the ACO may serve a wide range of patients, but only be held accountable from a shared savings perspective for those individuals who have a meaningful connection to the delivery system's provider base; for other beneficiaries, perhaps the ACO could be reimbursed through a care management payment.

To promote either a Pioneer duals pilot or a community-ACO model, data is key, specifically the following:

- **Integrated Medicare/Medicaid data sets**: Ensuring that the data delivered from CMS and the state are provided in as uniform a fashion as possible and on similar timelines
- **Required Participation in Regional Health Information Exchanges:** Montefiore possesses only partial information about ACO beneficiary utilization because once individuals seek services outside of our system, we generally do not have regular access to this information on a real-time basis. However, if providers in a county with a Regional Health Information Exchange were required to transmit data to the RHIO in a standard format and timeframe, it would greatly increase transparency and improve the ability of ACOs to coordinate across multiple payers and settings.
- **Access to behavioral health data:** Having information about the behavioral health needs of attributed beneficiaries in advance of demonstration years will facilitate more comprehensive care management.

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Stimulating Strategies to Focus on Chronically Ill Beneficiaries

We believe that the underlying principle of the recently proposed The Better Care, Lower Cost Act, introduced by Senator Ron Wyden–to improve care integration for chronically ill Medicare beneficiaries–could be applied to the ACO concept. Presumably ACOs are already initiating their own programs to address this population; the Montefiore ACO has a robust care guidance approach for serving beneficiaries with a range of chronic conditions. Yet CMS could go a step further to move ACOs in this direction by explicitly requiring or encouraging the management of chronically ill beneficiaries. For example, CMS may make available an enhanced care management fee to serve beneficiaries with HCC scores above a certain threshold or, at a minimum, distribute guidance on best practices for isolating the cohorts of patients who benefit from such interventions.

The Pioneer model has already achieved impressive results in the first years of operations. With the modifications described above, intended to 1) expand the reach and community impact of ACOs, 2) maximize long-term financial sustainability, and 3) support even more comprehensive care management, the model can even more effectively improve patient experience of care, positively impact population health, and lower costs for millions of Medicare FFS beneficiaries across the country.

Thank you again for the opportunity to provide this input. I am available to follow-up on any of these issues. In addition, please feel free to have your staff reach out to my staff, Kate Rose, Assistant Vice President of Public Policy and Government Relations, as needed. She can be reached by phone at (718) 920-6647 or by email at karose@montefiore.org.

Sincerely,

Steven M. Safyer, MD
President and CEO

CC: Jonathan Blum, Principal Deputy Administrator, Centers for Medicare & Medicaid Services
Aryana Khalid, Chief of Staff to the Administrator, Centers for Medicare & Medicaid Services
Patrick Conway, MD, Deputy Administrator for Innovation and Quality & CMS Chief Medical Officer
Mai Pham, MD, Acting Director, Seamless Care Models Group, Center for Medicare and Medicaid Innovation, Centers for Medicare & Medicaid Services

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February 28, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop 314G
200 Independence Ave., S.W.
Washington, DC 20201
Attention: CMS–1600–P

Dear Ms. Tavenner:

The National Association of Accountable Care Organizations (NAACOS) is writing because we have concerns about the future of the CMS Medicare Shared Savings Program (MSSP) and hope you will consider our comments helpful as you consider new regulations and operations policies this spring. NAACOS is owned and governed and represents the interests of 100 MSSP and Pioneer ACOs, with a great variety of organizational structure, geography, size, and experience present within its membership. To date, our ACO members have expended significant resources, in the form of both capital and time, to partner with CMS to make the ACO program a success. This letter focuses on a number of issues that NAACOS' membership has encountered during their participation in the MSSP and provides some recommended solutions. In particular, this letter addresses NAACOS concerns regarding (1) inherent adverse selection within current attribution, (2) risk adjustment for continuously assigned beneficiaries; (3) risk adjustment for ESRD patient category, (4) requirement for 2-sided risk in the second contract term; (5) minimum savings rate; (6) performance benchmarking and reconciliation; (7) quality benchmarking and (8) increase beneficiary affinity to the ACO. We believe that unless these problems are addressed, the Shared Savings Program will suffer from serious attrition and we as a nation will lose important momentum towards lowering costs and improving quality.

1. Adverse Selection within Current Attribution and Risk Adjustment Models.

Issue: Per current CMS policy, an ACO's average historical benchmark is calculated by identifying individuals who have received a plurality of their primary care services from a participant within an ACO during the past three "benchmark years." The costs for such individuals are then calculated for each year, adjusted to rule-out outlier expenses ("truncated"), and cost-adjusted to incorporate increases in cost ("trended forward," in the case of benchmark years one and two). The result of these calculations (the benchmark expenditures) is then risk-adjusted and weighted, with different levels of importance given to each year.

When an ACO's updated benchmark is calculated at the end of each program year, however, only beneficiaries who were assigned to the ACO during the previous program year are used in the

calculation. Because of this difference in the way in which beneficiaries are assigned to the ACO for purposes of calculating the historical benchmark versus the updated benchmarks, many MSSP ACOs have experienced what appears to be significant attrition of healthy patients, when in fact such patients simply have been well served by the ACO historically and do not need care on a yearly basis, but may have no plans to seek care outside the ACO in the future. This "attrition" of healthy patients affects the updated benchmark calculations and is not addressed by the current risk adjustment methodology.

Solution:

Option One: Irrespective of whether a specific beneficiary has received primary care from an ACO during the previous program year, CMS should allow all beneficiaries assigned to the ACO for purposes of calculating the historical benchmark to also be assigned to the ACO for purposes of calculating the updated benchmark and risk adjustment applicable to each program year. Beneficiaries would not be assigned to the ACO for the updated benchmark calculations if they received primary care during the previous program year from another ACO (or another non-ACO affiliated provider), are deceased, or would otherwise no longer be affiliated with the ACO. It is NAACOS' understanding that such a change would not require additional rulemaking but could be achieved through modifying CMS' policy in implementing the current regulations. Specifically a patient assigned during PY1 who has not filed any Medicare claims during PY2 anywhere should continue to be assigned to the original ACO.

Option Two: CMS could amend current regulations to provide that beneficiaries assigned to the ACO during the previous program year shall be used to both (1) calculate the updated program year benchmark, and (2) recalculate the historical benchmark. Such a method, while requiring a regulatory change, would ensure that an ACO's performance would be judged according to the care it actually provided to patients during a program year.

Either option will resolve the problem of benchmark "attrition" by more appropriately matching the data used in the updated benchmark with the data in the historical benchmark.

2. Risk Adjustment for Continuously Assigned Beneficiaries

Issue: For each ACO performance year CMS allows the benchmark for continuously assigned beneficiaries to be adjusted downward if the HCC risk scores fall from the prior year, but only allows upward adjustments for increases in the Demographic risk score. This policy has the effect of penalizing ACOs who improve the health status of their patients. This is especially true for ACOs that show meaningful improvements in their quality measures.

NAACOS is aware of and shares concerns expressed by CMS regarding potential for upcoding" claims to make patients seem sicker and thereby affect the ACO's risk scores. However, NAACOS notes that because such claims are submitted directly to CMS, such “upcoding” would be significantly more difficult than in the Medicare Advantage program.

Solution: CMS should allow risk adjustment to both lower and raise an ACO's risk scores for both newly and continuously assigned beneficiaries using data from both the current and prior year in addition to allowing such adjustments for newly assigned beneficiaries. This would (1) create greater parity with the risk adjustments allowed with Medicare Part C, (2) allow ACOs to be evaluated for the

true disease states of their patients, (3) allow for declines in disease states that are both inside and outside the ACO's control, and (4) remove incentive to avoid patients whose assigned risk scores do not reflect the true costs of caring for them. NAACOS is happy to discuss further protections that could be implemented surrounding this change.

3. Risk Adjustment for ESRD Patient Category

Issue: In development of the benchmark and in determining the performance of ACOs CMS classifies patients into four categories (ESRD, Disabled, Aged/Dual, and Aged/Non-Dual). These categories are reasonable given the different costs associated with treating each of these populations. The issue is that if ACOs excel in diabetic quality metrics they will have fewer patients with ESRD over time. The current program structure has the effect that CMS receives 100% of these savings.

Solution: CMS should allow patients with this condition to be grouped within the other categories in the same fashion as other patients with costly conditions.

4. Requirement for 2-sided risk in second contract cycle

Issue: NAACOS believes that reforming healthcare through Accountable Care Organizations is a long-term journey whose success will be measured in 5-10 years not three. Developing and implementing an ACO requires substantial capital to pay for start-up expenses including up to 21 months of operating capital before any chance of return is realized. These costs, estimated to average $4 million, invoke a substantial risk for the new ACO. The MSSP Contracts are for a 3 year term and ACOs choose whether to operate under the rules of Track1 (1-sided risk) or Track 2 (2-sided risk). Only a very small number of ACOs have applied for the Track 2 program. Based on our discussions with groups this is due to a number of factors including: (1) the newness of the program (i.e. development of benchmarks, risk adjustments, OACT calculations, truncation adjustments, etc.) (2) CMS's ability to change program terms after the contract is signed. (3) lack of control over changing community standards in care (4) lack of control over local costs per unit of care (i.e. changes in wage indexes) (5) the increase in the shared saving rate from 50% to 60% is insufficient to offset the risks of loss. Additionally, only a minority of the 2012 ACOs are experiencing savings above the Minimum Savings Rate. This means that the majority of ACO have yet to see any return on their sizable investment. Track 2 not only adds significant risk with little increase in the possibility of shared savings but it also may require additional licensing and regulatory oversight in some states. Our discussions with members and non-members indicate that only a small percentage is interested in signing a new contract if it includes the current 2-sided risk model. Further, NAACOS has seen NO data to indicate that bearing risk in addition to the start-up and operational costs would yield additional savings for the Medicare Program. In fact, reducing the number of ACOs may have the unintended consequences of lowering the overall savings for the MSSP program and losing the increased quality of care that comes with ACOs.

Solution: NAACOS is suggesting several options in order of our preference.

Option 1 is to simply permit an ACO to choose between the current Track 1 and Track 2 options in their second contract year. This gives the greatest flexibility to fit an ACO's financial and operational capabilities with a risk track.

Option 2 is to permit renewing ACOs to elect the Track 1 methodology for the first 2 years of the second contract and require them to conform to Track 2 rules for the third year or exit the program.

Option 3 would require successful ACOs (those with shared savings in Year 2) convert to Track 2 but others remain in Track 1 for the second contract year.

5. Minimum savings rate requirement (MSR) in Tracks 1 and 2

Issue: ACOs are committed to improving care and lowering costs for Medicare Beneficiaries and are making huge investments to build the financial, IT, and clinical infrastructure to succeed. We believe CMS should be doing everything it can to help an ACO succeed by sharing any and ALL savings that accrue to the Medicare Program. In establishing the MSR the statistical likely hood of any savings was lowered to account for random variation and prevent at all costs CMS from paying for savings that may not have been due solely to the ACOs operations. In Track 1, the MSR are from 2%-3.9% depending on size and a flat 2% for Track 2. However, variance can work the other way too and it could be argued that ACOs should be paid for any savings where the actual was lower than 2%-3.9% of the target. An ACO could show savings and not achieve the MSR in all three years and lose the savings due to statistical randomness yet when all three are combined, their savings would be statistically significant. The MSR is an arbitrary limit on savings that stacks the deck against the ACO and should be eliminated or modified.

Solution: NAACOS is suggesting several options in order of our preference.

Option 1 would eliminate or reduce the MSR to 1% in the calculation of shared savings. This would return maximum savings to the ACOs but still avoid substantial overpayments.

Option 2 would establish MSRs based on the cumulative beneficiary count over 3 years and provide interim shared savings over 1% in both tracks. CMS would then reconcile at the end of year 3 to the aggregate MSR.

6. Performance benchmarking and reconciliation process

CMS has made great strides in explaining the methodology of creating historical benchmarks and updating through reconciliation. While the process is highly complex and undiscernible to many, there is no reason to doubt that CMS is applying it equally to the historical data and to the performance year data. The adjustments for sequestration were made to minimize the impact on ACOs financially. However, the complexity and the inability of ACOs to track their progress on a monthly/quarterly basis is most vexing problem facing the ACO program and is a result of insufficient data elements, incomplete quarterly reporting and unpredictable retrospective assignment of beneficiaries to the ACO. In addition, costs trends are known to vary by region and can positively or negatively affect the final reconciliation benchmark for the ACO. NAACOS will recommend in another section how CMS/CMMI can experiment with improvements to the alignment and benchmarking process but believes there are several structural improvements that could be applied to the current process. We do not favor a replacement of the retrospective alignment with a prospective model like in the Pioneers. Retrospective alignment provides in the end the fairest way to calculate shared savings for the ACO.

Solution:

The first and most important improvement needs to help the ACO know accurately how well it is doing on PMPM cost trends. This can come from more complete eligibility data and Claims and Claims Line Feed (CCLF) data being provided and improvements to the quarterly reports. A complete list of these recommendations is included in the NAACOS Data White Paper, previously submitted to CMS. The second recommendation to improve the process is to speed up the calculation so that no later than 6 months from the end of a performance year, the final reconciliation is available to the ACO.

7. Quality benchmarking

Issue:

NAACOS continues to be concerned with the (1) lack of comparative FFS data and ACOs being compared to themselves versus similar FFS non-ACO practices, (2) instability of certain measures, (3) statistical impossibility of an ACO achieving 100% of quality payment, (4) absence of regional variation, (5) lack of any recognition or credit for quality improvement and (6) overall reporting burden on the ACOs. The 2012 GPRO quality measures and benchmarks are set based upon the performance of the highest quality Group Practices in the country combined with the ACOs themselves. This is inconsistent with the intent of the legislation which was to fairly compare ACOs to comparable FFS practices. Additionally, the clustering of many ACO metrics is still a problem and the arbitrary flat percentage has created unattainably high thresholds which will unfairly reduce hard earned savings of the ACOs. The benchmarks needed for full payment (90%tile level) include a 100% actual score for influenza, pneumococcal, colorectal screening and mammography (99.56%). These actual scores are not possible from a random sample of a large population. Further, it needs to be recognized for the next 3-5 years that quality varies considerably across the country and medical practices cannot be expected to conform to a single national standard in several years. Lastly, quality improvement has been the recognized national goal for over a decade and is embedded into virtually every healthcare organization, yet CMS gives NO recognition to improvement for purposes of earning shared savings. We see this as both a major conceptual and practical shortcoming to the ACO quality benchmarking and needs to be rectified in future rulemaking.

Solutions:

(1) It is in the regulatory authority of CMS to adopt a model of benchmarking based on a pure comparison to FFS practices without ACO data and we encourage CMS to do so in 2014.
(2) CMS should remove or modify some of the clustered measures for which there are not adequately established empirical norms.
(3) Arbitrary levels of achieving 100% of any actual score must be adjusted to reflect the realities of outlier/exceptions in real world practice and be recognized by high performing practices as moderately achievable.
(4) We do not object to the ultimate goal of a single national standard but strongly believe that CMS should adopt a transition plan that in the interim years, use quality benchmarks with a blend of national and regional averages.
(5) CMS has the data now to begin measuring an ACO's improvement in quality metrics and we recommend that for 2014 reconciliations, ACO should be permitted to achieve full savings if

either they achieve the required thresholds of the metrics OR achieve at least a 2% overall improvement of their combined score from the previous year.

(6) The science of quality measurement is growing and new measures that have been tested and accepted to industry standards should be used in the ACO program. However, the cost and human burden of quality measure submission and auditing is a huge financial burden on the ACOs and should not be increased by additional measures. CMS has plenty of opportunity to replace existing measures with new ones and should adhere to that principle in the coming years.

8. Increase beneficiary affinity (stickiness) to the ACO

Issue:

The large churn of aligned beneficiaries and the unpredictability of payback is the most often complaint we hear from ACOs. The complex, restricted, and highly regulated communication with the beneficiaries is a disincentive to building relationships.

Solution:

We recommend CMS allow a beneficiary, when in the PCP's office, to formally establish that PCP as their primary care physician and be given a card with contact information and after hours contacts. They could further be given the ACO's network physicians' names and contacts as MA plans and private insurers do. Finally, the PCP would be required to provide a written wellness plan and contact the beneficiary at the critical times in the plan.

Responding to the CMMI RFI

We are aware of the Request for Information on new Pioneer and other higher risk payment models and have responded in a limited way to the online questionnaire. However, we generally do not support the expansion of the MSSP program to require conversion to 2-sided risk or alternative risk models until some of the problems with data and the policies above have been fixed. Further, we think some of the problems with the MSSP program policies and data are so significant, that CMS must find a way to bring more stability, predictability and savings success to the Pioneer and MSSP program before launching new ACO models through CMMI. We think the Secretary should utilize the wide discretion of Section 3021 to test new payment and delivery models within the confines of the MSSP. The wide range of sizes and types of MSSPs is a perfect "laboratory" for introducing and testing solutions like waiving patient copayments for primary care, incentives to share savings with Part D plans, new quality measures, data sharing models with HIEs, data clearinghouse for eligibility notifications, increasing patient affinity by declaration of PCP, regional benchmarking and regional benchmark trending. Finally, as the MSSP expands, CMMI should consider additional advanced payment and start-up assistance.

Conclusion

In closing, NAACOS believes that after almost two years of experience, the MSSP Program can still achieve its goals but without the above changes, it will begin to see considerable attrition and lose its

current momentum. Adjustments are to be expected in large undertakings like this and we should not forget that provider engagement will only be sustained if significant numbers of the participating ACOs earn enough savings by year three to replenish the capital they have invested and allow participating providers to be rewarded for their efforts. CMS can now take action to help these ACOs achieve success and remain in the program. Long delays in addressing the problems outlined above will undoubtedly slow the growth of the program and lead to considerable attrition. This will have both a deleterious effect on the quality of care for beneficiaries and slow the advancement of population based health reform. We look forward to continuing our partnership with CMS and thank you for your consideration.

Sincerely,

Clifton Gaus

CEO

Cc: Jonathan Blum

Patrick Conway

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

March 1, 2014

VIA ELECTRONIC SUBMISSION:

RE: Request for Information: Evolution of ACO Initiatives at CMS

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to provide comments in response to the Request for Information (RFI) for the Evolution of Accountable Care Organization (ACO) Initiatives at CMS. NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries.

Discussion: Enhancing ACOs - Achieving Greater Integration and Financial Accountability

Medications are the primary intervention to treat chronic disease, and are involved in 80% of all treatment regimens.[1] Medicare beneficiaries with multiple chronic illnesses see an average of 13 different physicians, have 50 different prescriptions filled per year, account for 76 percent of all hospital admissions, and are 100 times more likely to have a preventable hospitalization.[2] Yet, medication management services are poorly integrated into existing healthcare systems, including ACOs. Poor medication adherence alone costs the nation approximately $290 billion annually – 13% of total healthcare expenditures – and results in avoidable and costly health complications.[3] Thus, given the importance of medications in achieving patient care outcomes and lowering overall healthcare costs, it is critical that CMS adopt policies that: (1) encourage greater care integration across the healthcare continuum; and (2) promote financial accountability for safe and appropriate medication use within ACOs.

A. <u>Important Role of Medication Management & Related Services</u>

NACDS shares the view advanced by pioneers of ACO movement in that many of the deficiencies in the U.S. healthcare system are reflections of the disjointed and poorly coordinated care that patients receive as they move across settings and providers: more

[1] http://www.pcpcc.org/sites/default/files/media/medmanagement.pdf
[2] Ibid
[3] http://www.dmhc.ca.gov/library/reports/news/rci/totpb.pdf

frequent and flawed care transitions, failures of communication, and errors.[4] Fragmentation of care is never more apparent than with respect to the chronically ill and high-risk patients. The ACO model conceptually holds promise to provide care that is coordinated across professionals, facilities, and support systems; continuous over time and between visits; tailored to the patients' individual needs and preferences; and based on shared responsibility with patients for optimizing health.[5] In particular, NACDS applauds the early results of CMS' ACO demonstration projects.

A growing body of evidence suggests that when physicians, nurses, pharmacists, and other healthcare professionals work collaboratively, better health outcomes are achieved. Pharmacies in particular provide access to highly-trained and highly-trusted health professionals. The unique reach and access points of pharmacy provide a means of continuous care and oversight between scheduled doctor visits. As such, community pharmacies have increasingly provided a suite of medication management and related services, including Medication Therapy Management (MTM), disease-state monitoring and patient self-management, adherence interventions, medication synchronization, transitions of care, immunization programs, chronic care and wellness programs, and patient engagement, among others.

Recent systematic reviews have highlighted the beneficial role of the aforementioned pharmacy based services in team-based care.[6] Yet, experts have noted the lack of integration, to date, of community pharmacy services into emerging models of care such as ACOs.[7] Smith and colleagues noted:

> Pharmacists can help meet the demand for some aspects of primary care and can contribute to the efficient and effective delivery of care. Thus, they should be included among the health professionals who are called on to mitigate the projected primary care provider shortage.[7]

The potential benefits of integrating medication management services have been emerging in the last couple of years. For example:

- CMS' own report from 2013 found that Part D MTM programs consistently and substantially improved medication adherence and quality of prescribing for evidence-based medications for beneficiaries with congestive heart failure, COPD, and diabetes. The study also found significant reductions in hospital costs, particularly when a comprehensive medication review (CMR) was utilized. This included savings of nearly $400 to $525 in lower overall hospitalization costs for beneficiaries with diabetes and congestive heart failure. The report also found that MTM can lead to reduced costs in the Part D program as well, showing

[4] Fisher,Eet.al (2006)."Creating Accountable Care Organizations: The Extended Hospital Medical Staff,." *Health Affairs.* Retrieved from http://content.healthaffairs.org/content/26/1/w44.full.pdf.
[5] http://iom.edu/~/media/Files/Activity%20Files/Workforce/NursingCredentialing/2013-NOV-11/2%20Ken%20Kizer%20pdf.pdf
[6] http://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf
[7] http://content.healthaffairs.org/content/32/11/1963.full

that the best performing plan reduced Part D costs for diabetes patients by an average of $45 per patient.

- A study published in the January 2012 edition of *Health Affairs* identified the key role retail pharmacies play in providing MTM services. The study found that a pharmacy-based intervention program increased adherence for patients with diabetes and that the benefits were greater for those who received counseling in a retail, face-to-face setting, as opposed to a phone call from a mail order pharmacist. The study suggested that interventions such as in-person, face-to-face interaction between the retail pharmacist and the patient contributed to improved behavior with a return on investment of 3 to 1.

- The Congressional Budget Office (CBO) has also acknowledged that medication use reduces healthcare costs in other parts of the Medicare program. The CBO recently revised its methodology for scoring proposals related to Medicare Part D and found that for each one percent increase in the number of prescriptions filled by beneficiaries there is a corresponding decrease in overall Medicare medical spending. When projected to the entire population this translates to a savings of $1.7 billion in overall healthcare costs, or a savings of $5.76 for every person in the U.S. for every one percent increase in the number of prescriptions filled.

- Several states have implemented MTM programs and have seen notable program savings for both the state and the enrolled beneficiaries. For example, the North Carolina ChecKmeds program uses specially trained personal pharmacists in communities throughout North Carolina to provide MTM services to all Medicare Part D recipients ages 65 and older. The program has generated savings of approximately $66.7 million in overall health care costs for the state which included $35.1 million from avoided hospitalizations and $8.1 million in drug product cost savings.

- Similar results were seen with the implementation of the Iowa MTM pilot program which utilizes pharmacists to help patients manage their medications and improve patient adherence through education and continued monitoring. In the first twelve months of implementation, the state generated savings of approximately $4.3 million in avoided costs which consisted of $1.18 million from drug product costs savings and approximately $3.07 million from fewer hospitalizations, fewer emergency room visits, and fewer office visits.[8]

Thus, medication management services provided by community pharmacists improves patient care, enhances communication between providers and patients, improves collaboration among providers, optimizes medication use for improved patient outcomes,

[8] Both North Carolina ChecKmeds Program and the Iowa MTM Pilot program use Outcomes Pharmaceutical Health Care for the management of their MTM programs. All savings have been provided by Outcomes.

contributes to medication error prevention, and enables patients to be more actively involved in medication self-management.

B. Integrating Accountability for Medicare Part D Expenditures into ACOs

NACDS supports a holistic approach to healthcare transformation, and believes that the successful alignment of structural modifications to the Medicare ACO program will lead to cost avoidance and reduced healthcare spending. Thus, NACDS is supportive of CMS' efforts to increase accountability for ACOs to integrate Part D expenditures as part of their approach to care delivery and healthcare transformation.

Without full integration of medication management, ACOs will remain fragmented and not achieve their full potential. To date, several CMS-backed Pioneer ACOs have proactively forged relationships with community pharmacies in order to deliver better performance. However, several barriers have been identified to the more widespread inclusion of pharmacist-provided medication management services into ACOs which need to be proactively addressed to achieve CMS' goal of enhanced integration. These include:

- **Quality Performance Standards to Track Gaps in Medication Use and Safety.** In order to truly integrate accountability for Medicare Part D expenditures, the current quality measurement standards must be augmented to include measures for medication management. CMS should consider inclusion of medication measures currently adopted in the Medicare Star Rating program, which includes three measures on medication adherence, gaps in care, and high-risk medication use in the elderly, as well as a proposed measure on MTM performance (including Comprehensive Medication Reviews). A diverse group of stakeholders, including the American Heart Association, have urged CMS to adopt the aforementioned medication adherence measures in other federal programs, given their importance to delivering better care at lower cost.

- **Bilateral Data Sharing**. Because data integration is fraught with business and IT challenges, it is essential to align the financial incentives with care integration. With successful alignment, team members will be encouraged to invest in bi-directional IT systems, providing the means to perform quality, performance and financial assessments. Such systems can also enhance coordination across care settings, providing actionable and meaningful clinical information to providers and community pharmacists with respect to medication adherence, identifying drug-related problems, gaps in care, immunizations, and other potential care opportunities. Thus, aligning incentives for bilateral data-sharing between community pharmacies and ACOs can lead to enhanced medication management and overall better health outcomes.

- **Build Appropriate Payment Mechanisms.** Pharmacists are not currently recognized as providers within the Medicare program, and consequently receiving compensation for evidence-based screenings, preventive care services and medication management has proven challenging. It will be important to align incentives so that pharmacists are able to provide critical services on behalf of ACOs.

Conclusion

For these reasons, medication management services provided by pharmacists should be considered a critical factor in the success of any ACO program and CMS should therefore adopt policies to enhance the inclusion of community pharmacists in the next generation of CMS ACOs to improve health outcomes and reduce healthcare costs related to chronic conditions. In particular, we are supportive of CMS' efforts to align incentives and integrate accountability for Medicare Part D expenditure into ACOs. NACDS thanks CMS for the opportunity to comment on this RFI for the next generation of CMS ACOs and looks forward to working with you on this very important program.

Sincerely,

national partnership
for women & families
Because actions speak louder than words.

March 1, 2014

U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
Center for Medicare and Medicaid Innovation
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Request for Information: Evolution of ACO Initiatives at CMS

To Whom It May Concern:

The National Partnership for Women & Families appreciates the opportunity to comment on the Department's request for information on the evolution of Accountable Care Organization (ACO) initiatives at the Centers for Medicare and Medicaid Services (CMS). The National Partnership represents women across the country who are the health care decision-makers for themselves and their families and who want to ensure that health care services are both affordable and of the highest quality. We are deeply invested in improving the quality and value of health care and committed to ensuring that new models of care delivery and payment provide women and families access to comprehensive, high quality, and well-coordinated patient- and family-centered care.

We commend the work CMS is undertaking to move our health care system toward more accountable care. We understand that CMS is considering a range of potential new risk arrangements and structures for its ACO initiatives, with the goals of attracting new participants to its programs and improving ACO efficiency, care integration, and accountability. Our comments focus on this second goal, evolution of the ACO model, as captured in Section II of the RFI. Specifically, we offer recommendations that (1) address how current ACO programs and can be evolved to increase integration of Medicaid expenditures and outcomes in accountability models and (2) reflect fundamental consumer policy priorities that must be central to continued development of ACO initiatives and other alternative payment model programs.

If you have any questions about our comments and recommendations, please contact Lauren Birchfield Kennedy, Senior Health Policy Counsel, at lkennedy@nationalpartnership.org or (202) 986-2600.

Sincerely,

Debra L. Ness, President

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Section II: Evolution of the ACO Model

Subsection C: Integrating Accountability for Medicaid Care Outcomes

Priority Medicaid Populations

The RFI requests recommendations for integrating accountability for Medicaid care outcomes and recommendations for priority populations within Medicaid (Subsection C, Questions 1 and 2). The National Partnership supports CMS' interest in transforming care for Medicaid beneficiaries by pursuing innovative care delivery approaches for this population. Specifically, we encourage CMS to consider how ACO initiatives can be used to improve the quality, outcomes, and value of care provided to childbearing women and newborns through Medicaid and the Children's Health Insurance Program (CHIP). CMS should identify childbearing women and newborns as priority Medicaid populations for several reasons:

- Scale. The entire population experiences maternal-newborn care at the beginning of life, as do about 84 percent of the nation's women who give birth once or more in their lifetime.

- Utilization and Cost. With nearly four million births annually in the United States, maternal-newborn care is a major segment of our health care system. Medicaid is the primary payer for about 44 percent of these births, a proportion that has risen steadily in recent years. Combined care of childbearing women and newborns is the most common and costly condition in U.S. hospitals for Medicaid (as well as for private payers and all payers). As a focus for quality improvement, prenatal through postpartum/newborn care is a well-defined episode of care.

  Although most mothers and newborns are healthy, current care patterns are costly. A report from Truven Health Analytics found that average Medicaid payments for all maternal-newborn care in 2010 were $9,131 for vaginal births and $13,590 for cesarean births, with private insurers paying about double those amounts. (With inflation, present payments are much higher.) The analysis found that the cost of maternity care is highly concentrated in the brief window of the childbirth hospitalization: from 70 percent to 86 percent of all maternal-newborn payments were for this phase of care, depending on payer source and type of birth.

- Quality Improvement Opportunities. The care of childbearing women, a predominantly healthy population, has become procedure intensive. Six of the ten most common hospital procedures are associated with childbearing women and

newborns, and cesarean section is the nation's leading operating room procedure. The U.S. national cesarean rate (33 percent) far exceeds the upper limit recommended by the World Health Organization (15 percent). Researchers report that broad practice variation across hospitals, clinicians, and geographic areas for procedures such as labor induction and cesarean section reflects differences in market forces and practice style rather than differences in the needs and preferences of care recipients. Overuse of procedures and services is a major concern in a system that has historically rewarded volume over outcomes and value. Underuse of many beneficial non-invasive practices is also common. Thus, there is clearly room for improvement when it comes to the quality of the maternity care provided to the maternal-newborn population.

Ensuring that women and their children receive high quality maternity and newborn care is particularly important given the longer-term and potentially lifelong effects of care provided before, during, and after pregnancy. For example, the burgeoning literature on developmental origins of health and disease calls for caution during the prenatal to the early newborn period, when rapidly developing organ systems are especially sensitive and vulnerable. Systematic reviews show a roughly 20 percent increase in childhood obesity, type 1 diabetes, asthma, and allergy in cesarean-born babies.

- Prenatal Opportunities for Engaging Activated Consumers. The prenatal period offers an important opportunity for relatively young, highly motivated women with limited previous health care experience to become engaged health care consumers. Through shared decision making processes, care planning, and guidance in taking responsibility for self-care, these women can go on to manage care effectively for themselves, their children, and others.

Innovative payment and delivery systems that incentivize a shift in maternity care practice style, so that provision of maternity and newborn services reflects evidence-based best practices, can result in significant gains in the quality, outcomes, and value of maternal-newborn care. For example, concurrent gains in both maternal health outcomes and cost savings can be achieved by reliably supporting the innate hormonally-driven capabilities of childbearing women and their fetuses/newborns (e.g., prioritizing spontaneous onset of labor, delaying admission until labor is well established, providing non-pharmacologic support for labor progress and comfort, awaiting and encouraging women to respond to their own pushing sensations, keeping mothers and babies skin-to-skin after birth, etc.). The 2014 joint Obstetric Care Consensus statement "Safe Prevention of the Primary Cesarean Delivery" from the American College of Obstetricians and Gynecologists and the Society for Maternal-

Fetal Medicine identifies many evidence-based practices that can improve labor care and reduce the use of interventions and costs of care.

Compelled change in maternity care practice style, to ensure provision of quality, evidenced-based care, can be achieved through required reporting on performance and quality measures. Indeed, performance reporting is a critical element of maternity care quality improvement. Medicaid ACOs and alternative care-delivery and payment models should use performance measures that are relevant to a large segment of the maternal-newborn population. The Joint Commission has mandated reporting of its core Perinatal Care measure set by hospitals with 1,100 or more births per year from January 2014, with possible future extension to facilities with fewer births. Of and in addition to the Joint Commission's core set, the following measures are particularly relevant to the Medicaid maternal-newborn population:

- Elective Delivery (unwarranted elective delivery before 39 weeks' gestation). This measure has been endorsed by the National Quality Forum (NQF) and is included in the Joint Commission, Medicaid Adult, and Inpatient Quality Reporting core measure sets.
- Cesarean Section (cesarean rate in low-risk first-birth women). This measure is NQF-endorsed and is included in the Joint Commission and CHIPRA Child core measure sets.
- Exclusive Breast Milk Feeding (baby has been exclusively breastfed at hospital discharge). This measure is NQF-endorsed and is included in the Joint Commission core measure set.
- Healthy Term Newborn. This measure is NQF-endorsed, though it is currently undergoing revision as "Unexpected Newborn Complications, complications during or after birth in low-risk newborns."
- Vaginal Birth after Cesarean (VBAC), Uncomplicated (rate of VBAC among women without complications at birth and with previous cesarean birth). This measure is an Agency for Healthcare Research and Quality Inpatient Quality Indicator.

Various additional quality measures in the pipeline between measure specification and endorsement would also support these aims. These include the AMA Physician Consortium for Performance Improvement's Spontaneous Labor and Birth measure, as well as several in the Women's Health and Perinatal Nursing Care Quality measure set of the Association of Women's Health, Obstetric, and Neonatal Nurses.

We also note that there is a significant need to fill major gaps in quality measures for this population. Development and endorsement of additional quality measures for maternal health services could lead to important improvements in health outcomes and reductions in unnecessary or avoidable costs. For example, to evaluate the full episode of maternity care and contribute to the quality of postpartum care, there is a need for a woman-reported composite measure of new-onset morbidity at about six weeks' postpartum. There is also a need for Maternity CAHPS adaptations of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) facility, provider, and health plan surveys, as the generic surveys cannot adequately capture the experience of care for this population. As the ACO programs continue to evolve, we urge additional investment in quality measurement development, endorsement, and application, particularly for the maternal-newborn population.

Finally, to advance the above aims, ACOs held accountable for Medicaid maternal-newborn populations should consider contracting with freestanding birth centers and providing incentives to low-risk women to consider this care option. For many women and newborns, utilization of freestanding birth centers is associated with very high levels of satisfaction and can lead to better care, outcomes, and value. Moreover, access to these facilities would advance broader ACO goals of reducing hospitalization. Such contracts also would ensure that birth centers are integrated into higher levels of care, with access to consultation, collaboration, and transfer, as appropriate. We recommend contracting with birth centers that are accredited by the Commission for the Accreditation of Birth Centers and note that the Affordable Care Act includes provisions for Medicaid reimbursement of freestanding birth centers and providers who practice in them.

In sum, with respect to the future direction of and priority populations for Medicaid-integrated ACOs, we encourage CMS and its partners to:

- Prioritize quality improvement for the care of childbearing women and newborns;
- Encourage development of evidence-based protocols;
- Require reporting on priority performance measures that are relevant to large segments of the maternal-newborn population and that will lead to improved performance; and
- Consider contracting with accredited freestanding birth centers.

Considerations for Integrating Accountability for Medicaid Populations

Overall, Medicaid beneficiaries – who tend to have more complex health needs and often face greater barriers to care – may have the most to gain from an integrated system that provides more comprehensive, coordinated care. It is crucial, however, to ensure that any new ACO model for Medicaid beneficiaries is truly accountable for meeting the health care needs of this population. Thus, CMS requirements must maintain strong consumer protections and ensure ACOs have adequate infrastructure to meet Medicaid beneficiaries' needs. Specifically:

- It is crucial that all ACOs aiming to serve Medicaid beneficiaries and dually eligible beneficiaries are able to manage and coordinate the full spectrum of dual eligibles' needs, and include within their network providers with expertise in managing this population's unique needs.
- CMS should encourage ACOs to provide intensive care management and home-based primary care services, and include home health agencies, assisted living, SNFs/NFs, and other providers of long-term services and supports in their networks to maximize coordination of care for dual eligibles.
- Lastly, CMS should strive to identify ways to ensure that ACOs meaningfully partner with existing community-based service providers to coordinate and deliver the community-based services that are especially critical for many Medicaid beneficiaries.

We urge CMS to continue to work closely with consumer advocacy organizations as it considers expanding innovative care for this population. These organizations can help the agency ensure (1) that program requirements provide the appropriate protections for beneficiaries and (2) that information transmitted to beneficiaries meets their needs and addresses common questions.

Subsection D: Other Approaches for Increasing Accountability

The RFI requests comments on whether CMS should formalize an accountable care model where various service delivery and payment reform initiatives are combined. The RFI specifically identifies a potential model that tests comprehensive primary care reform within an ACO context. The National Partnership agrees that the most successful ACOs will be grounded in comprehensive, well-coordinated, and patient-centered primary care. Core elements of true primary-care reform must be a driving force of future ACO initiatives and designs. As CMS considers ACO models that include primary care reform components, we believe the Comprehensive Primary Care (CPC) Initiative is an excellent program from which to draw.

Overall, the success of an ACO will depend on the extent to which it engages patients and their families as full partners in their own care and supports their participation in health care decision-making. We urge CMS to ensure that the next generation of ACOs supports these partnerships. Specifically, ACOs, at all levels of care delivery reform, should support:

- Shared Decision-Making. Patients value and benefit from shared decision-making tools that can help them make good decisions about their care. Shared decision-making tools and processes can also improve the quality of care provided, particularly when there is considerable uncertainty or variation with regards to outcomes. High-quality decision tools can also be used, when available, to reduce unwarranted practice variation and to align care with the needs and values of patients themselves. We commend CMS for supporting shared decision-making in both the Medicare Shared Savings and Pioneer programs. As CMS considers new ACO approaches, we urge the agency to provider even more support for shared decision-making tools and processes through robust program requirements and quality measures.

- Collaborative Self-Management. Supporting patients (and family caregivers, as appropriate) in managing their health and chronic conditions is a key strategy not only for engaging patients as partners in their care but also for improving outcomes and reducing the need for more costly medical care. We strongly encourage CMS to require support for collaborative self-management in any new ACO initiatives.

- Care Planning. Individualized care plans are a core element of effective care coordination and we continue to support an emphasis on care planning in ACO requirements. We encourage CMS to think of them as *shared care plans*, which are jointly maintained and updated by patients, family caregivers, and members of their care team. Proactively and explicitly engaging an individual's family and caregivers in the development of a care plan helps to ensure that the individual's abilities, culture, values, and faith are respected and care instructions and care recommendations are more likely to be understood and followed. Ideally, care plans should also enable patient access to health information and patient ability to contribute to and correct health information to help manage their care and wellbeing. In the next generation of ACO initiatives, ACOs should be required to provide a patient-centered platform for health and care planning.

- Engaging Patients and Families in Care Design/Redesign. Patients and families have unique and valuable perspectives to share when it comes to designing or redesigning care delivery. Only by including consumer voices at the table can ACOs successfully design care in a way that truly meets the needs of patients –

particularly the most vulnerable patients. We urge CMS to include strong requirements and accountability for consumer involvement in ACO care design and redesign efforts.

- Engaging Patients and Families in Governance. Consumers must have a real voice in ACO governance and decision-making. As CMS considers the governance structures of new ACO initiatives and accountable care models, the agency must move beyond the requirements of the Medicare Shared Savings and Pioneer programs to promote more meaningful consumer engagement and participation in ACO governance.

Subsection E: Multi-Payer ACOs

The RFI requests comments on how CMS and other payers can focus reporting of quality measures on the most priorities while minimizing duplication and excess burden (Subsection E, Question 2). Expanding on our comments above on how utilization of quality measures can advance outcome and value goals, we urge CMS, in any new ACO initiative, to ensure a robust focus on quality measurement and improvement.

Specifically, we urge CMS to:

- Make available quality information that is meaningful, understandable, and accessible to those receiving care;
- Improve the availability of meaningful measures that (1) support informed decision-making by patients and families and (2) propel movement toward a patient-centered delivery system that results in improved clinical outcomes; and
- Stratify and report clinical quality measures by disparity variables such as race, ethnicity, language, socioeconomic data, disability status, sexual orientation, and gender identity data.

Further, we strongly urge CMS to prioritize the collection of patient experience and patient-reported outcomes measures. Measuring patient experience is often the only way to evaluate elements of care that patients and family caregivers identify as most important to improving their health outcomes. Gauging a patient's experience of care is especially important for those who have multiple conditions and for whom condition-specific quality measures cannot provide an adequate picture of the total quality of care received. Family caregiver experience data is also particularly helpful in assessing experience of care for those patients with cognitive impairment that prevent them from

talking about their own experience, or provide insights into areas patients themselves may be reticent to discuss.

We also recommend that CMS prioritize use of quality measures that have been endorsed by a consensus-based entity, such as the National Quality Forum (NQF). As a multi-stakeholder organization, NQF operates in a fully transparent, inclusive manner to reach consensus. Its consensus-based process for evaluating and endorsing quality measures reflects strong multi-stakeholder efforts and consensus building. Involving multiple stakeholders, including representatives from the consumer, clinical, hospital, and purchaser communities, in the approval process helps assure broad acceptance of the endorsed measures by consumers, providers, and public and private payers. As a result, NQF-endorsed measures have broad support and wide applicability for quality improvement and accountability across both public and private plans. Moreover, utilization of NQF measures, which are used in both the public and private sectors, can help minimize duplication, reduce excess burden, and facilitate alignment. Promoting alignment and standardization ensures consistent measurement, reporting, and practice across ACO programs.

Additional Recommendations

Health Information Technology and Meaningful Use

Health Information Technology (H IT) is an essential foundation for delivery system and payment reforms. To be successful, ACOs and other new models of care delivery require provider and patient ability (1) to share data and (2) to integrate data across various sources (i.e., doctors, hospitals, laboratories, pharmacies, registries, and patients) and across various types/platforms (i.e., clinical, claims, and patient-generated data). The exchange of health information is fundamental to achieving the improved quality, care coordination, patient-centeredness, and cost reduction goals of ACOs.

The “Meaningful Use” Electronic Health Record (EHR) Incentive Program and the technical standards deployed through the parallel Office of the National Coordinator Certification program are currently accelerating the development of necessary standards and services to make care coordination across health systems easy and efficient for both providers and patients. For example, Meaningful Use is producing standardized data elements for critical records and processes of care that are foundational to successful ACO arrangements, including:

- Summary of Care Record. The eligible hospital or professional that transitions a patient to another setting of care or refers the patient to another provider of care provides a summary care record for 50 percent of transitions of care or referrals;
- After Visit Summary. Clinical summaries are provided for patients following each office visit;
- View, Download, Transmit (V/D/T). Patients have the ability to view online, download, and transmit to third parties their health information, and the criterion specifies the types of information that must be made available;
- Population Health Dashboard. Near real-time (vs. retrospective reporting) patient-oriented dashboards displaying lists of patients with specific conditions or filtering by various demographic or clinical variables for use for quality improvement, reduction of disparities, research, or outreach reports;
- Health Care Event Notification. Electronic notification of a significant healthcare event (arrival at an Emergency Department, admission to a hospital, discharge from an ED or hospital, or death), in a timely manner to key members of the patient's care team, such as the primary care provider, referring provider or care coordinator, with the patient's consent if required; and
- Patient Reminders. Use of clinically relevant information to identify patients who should receive reminders for preventive/follow-up care; reminders sent to these patients per patient preference.

With the next generation of ACO initiatives, we encourage CMS to require participating ACOs to demonstrate that a majority of its providers are meaningful EHR users. As of December 2013, nearly 90 percent of eligible hospitals had received an incentive payment and approximately 60 percent of eligible physicians were successful meaningful users. This infrastructure for health information exchange should be leveraged in the current and future ACO initiatives, as well as other innovative new payment and delivery models. Given the success of the Meaningful Use program, we strongly urge CMS to require that at least 50 percent of eligible primary care providers and 75 percent of eligible hospitals be meaningful users of HIT as a core requirement for becoming an ACO.

Additionally, to improve care quality and health outcomes, it is absolutely critical that health IT systems facilitate safe and secure sharing of information, not just between providers, but among patients, families, and other designated caregivers. Giving patients the ability to view, download, and transmit their own health information was a monumental advancement for consumers in Stage 2 of Meaningful Use. At minimum, ACOs should have standards and processes in place for beneficiaries to electronically

access their health information in a way that is aligned with the "View/Download/Transmit" criteria in Meaningful Use (at least among providers that are eligible for Meaningful Use). Consistent with Stage 2 Meaningful Use, ACOs should be accountable for having at least five percent of their patients accessing their health information online.

Consumer Protections

As CMS considers new ACO approaches, we urge the agency to ensure that strong consumer protections are not sacrificed in efforts to innovate and better integrate care. These goals are not mutually exclusive. This is of particular concern for Medicaid and dually eligible beneficiaries, but important for all individuals receiving care through an ACO. These protections include the following:

- Continuity of Care. CMS must ensure that beneficiary alignment or affiliation with an ACO does not create interruptions in ongoing care that cause significant hardships for beneficiaries or result in a reduction of needed services.

- Transparency and Notification. Regardless of how a new ACO is organized, we believe there must be full transparency of beneficiary alignment/affiliation. Beneficiaries have a right to know about any new financial incentives that may influence provider behavior and the care that is delivered. Beneficiaries also need to fully understand what they can expect from the ACO, including attributes that differentiate it from the fee-for-service model, like care coordination.

- Notice. CMS should ensure ACOs include adequate notice protections for beneficiaries that are consistent with existing requirements – specifically, notice of the availability of treatment options, the right to a second opinion, etc.; and

- Grievance/Complaints Processes. For any potential new approach, we believe ACOs must have in place a formal procedure for patients to voice grievances regarding treatment or care (such as the regulatory language for both Medicare Part D and Medicare Advantage). CMS should require ACOs to give notice to patients of their rights to file a complaint under the grievance procedures. CMS should also require ACOs to establish a process to track and maintain records on all grievances received and the disposition of each grievance. ACOs should report this information to CMS on a regular basis, and CMS should have a process in place to issue warnings, put an ACO on a corrective action plan, or terminate an ACO's participation.

Thank you again for the opportunity to comment on the evolution of ACO initiatives at CMS. We look forward to working with you to ensure that ACOs – and all new care delivery and payment models – are designed in ways that improve the quality and value of care and truly transform the way care is delivered.

Principles for Patient- and Family-Centered Care:

The Medical Home from the Consumer Perspective

As organizations representing a broad and diverse array of consumer interests, we believe that the following set of principles should guide the development and implementation of the medical home model of care.

1. **In a patient-centered medical home, an interdisciplinary team guides care in a continuous, accessible, comprehensive and coordinated manner.**
   - The patient is the center of the care team. Family members and other caregivers may also be a central part of the team.
   - The care team includes professionals inside the medical office or health center, as well as clinical and non-clinical professionals in the community.
   - The team provides initial and routine assessments of the patient's health status, and places a high priority on preventive care, care coordination and chronic care management to help patients get and stay healthy and maintain maximum function.
   - The care team is led by a qualified provider of the patient's choice, and different types of health professionals can serve as team leader.

2. **The patient-centered medical home takes responsibility for coordinating its patients' health care across care settings and services over time, in consultation and collaboration with the patient and family. The care team:**
   - Helps patients choose specialists and obtain medical tests when necessary. The team informs specialists of any necessary accommodations for the patient's needs.
   - Helps the patient access other needed providers or health services (including providers or health services not readily available in the patient's community, e.g., in a medically underserved area).
   - Tracks referrals and test results, shares such information with patients, and ensures that patients receive appropriate follow up care and help in understanding results and treatment recommendations.
   - Ensures smooth transitions by assisting patients and families as the patient moves from one care setting to another, such as from hospital to home.
   - Has systems in place that help prevent errors when multiple clinicians, hospitals, or other providers are caring for the same patient, such as medication reconciliation and shared medical records.
   - Has systems in place to help patients with health insurance eligibility, coverage, and appeals or to refer patients to sources that can be of assistance.

3. **The patient has ready access to care. The care team:**
   - Ensures that patients can schedule appointments promptly – on the same day if needed – and experience brief office waiting times.
   - Guarantees that a member of the medical home clinical team is available by phone, e-mail or in person nights, weekends, and on holidays. A responsible team member has ready access to the patient's information and is always able to communicate with the patient, using interpreter services and translated materials if needed.
   - Accommodates the needs of patients with limited physical mobility, English proficiency, cultural differences or other issues that could impede access to needed examination and treatment and patient self-management.
   - Facilitates patients' ready and appropriate access to services from other providers, such as mental health or reproductive health care providers. The medical home is not a "gatekeeper," but rather facilitates connections to other providers and services, as appropriate.

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4. **The patient-centered medical home "knows" its patients and provides care that is whole person oriented and consistent with patients' unique needs and preferences. The care team:**
   - Has ready access to the patient's complete, up-to-date medical history. The team also ensures that patients and authorized family caregivers have access to this information.
   - Takes into consideration the patient's life situation, including family and caregiver circumstances, his or her values and preferences, age, and home environment when making recommendations about the patient's health care and treatment plan.
   - Communicates with patients in culturally and linguistically appropriate ways.

5. **Patients and clinicians are partners in making treatment decisions. The care team:**
   - Helps patients and others designated by the patient understand their condition and the results of any medical tests or consultations with specialists.
   - Provides unbiased, evidence-based information on all treatment options, including possible side effects, costs, and the benefits and risks of different options (including alternative therapies), so that patients can make an informed choice that reflects their personal preferences.
   - Does not withhold information about treatment options from patients based on assumptions about ability to pay.
   - Provides patients with timely access to results of laboratory and other diagnostic tests through such means as telephone, email, fax, personal health records, or patient portals.
   - Makes use of e-reminders, especially for preventive care services.

6. **Open communication between patients and the care team is encouraged and supported. The care team:**
   - Communicates with patients in a way they understand and prefer. They encourage questions and two-way conversation that helps patients and their caregivers (when appropriate) effectively manage their health and be full partners in their health care.
   - Knows about and overcomes any language, cultural, literacy, or other barriers to effective communication with patients, family members and other caregivers.

7. **Patients and their caregivers are supported in managing the patient's health. The care team:**
   - Integrates culturally appropriate community-based support resources such as social services, transportation, peer support groups, and exercise programs.
   - Works with patients to develop their capacity to stay well and manage their health conditions.
   - Assesses and accommodates patients who are unable to effectively manage their own care because of cognitive or physical challenges, by working with family caregivers, legal surrogates or other sources of support.
   - Works with the patient or their caregiver to develop, plan and set goals for their care and helps the patient meet those goals.
   - Ensures that no treatment decisions are made without the patient's consent and understanding.

8. **The patient-centered medical home fosters an environment of trust and respect. The care team:**
   - Treats patients, family, and/or other caregivers with dignity and respect.
   - Guarantees that patients can trust that their personal health information is never shared or used without their knowledge.
   - Ensures that examinations and discussions with or about patients take place in a setting that affords appropriate privacy from other patients or staff.

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9. The patient-centered medical home provides care that is safe, timely, effective, efficient, equitable, patient-centered and family-focused. To accomplish this, the care team:

- Seeks out and encourages patient feedback on their experience of care, and uses that information to improve the quality of care they provide.
- Collaborates with patient and family advisors in quality improvement and practice redesign.
- Collects data on race, ethnicity, gender, primary language, and language services for each patient and records that information in a manner that can be reported and used to plan and respond to the health and language needs of patients in the practice.
- Regularly evaluates and improves the quality, safety and efficiency of its care using scientifically sound measures and reports that information to an entity that will make it publicly available in a way consumers can understand and access.
- Routinely undertakes efforts to identify and eliminate any disparities in the quality of care received by its patients.

These principles are provided in the context of patient-centered medical home initiatives, which should include changing the way providers are paid so they are both incentivized and adequately compensated for providing the high quality, patient-centered care envisioned in these principles.

Organizations subscribing to this statement of principles:

AARP
AFL-CIO
Alzheimer's Association
American Diabetes Association
American Hospice Foundation
Asian & Pacific Islander American Health Forum (APIAHF)
Bazelon Center for Mental Health Law
CMHI (Center for Medical Home Improvement) of Crotched Mountain Foundation
Center for the Advancement of Health
Childbirth Connection
Community Catalyst
Community Health Alliance of Humboldt – Del Norte (CA)
Consumers Union
Consumer Worker Coalition (MN)
Families USA
Family Voices
Institute for Family-Centered Care
Leadership Conference on Civil Rights
Medicare Rights Center
NAACP
National Alliance for Caregiving
National Consumers League
National Council of La Raza (NCLR)
National Family Caregivers Association
National Health Law Program (NHeLP)
National Partnership for Women & Families
National Women's Law Center
Peer Outreach and Education Team (Humboldt County, CA)
SEIU
Universal Health Care Action Network of Ohio
Western New York Association of Diabetes Educators (NY)

For more information, please contact the National Partnership for Women & Families at 202-986-2600, or visit www.nationalpartnership.org/medicalhome

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From: Andrew Wickman [mailto:ajwickman@mac.com]
Sent: Tuesday, March 04, 2014 1:37 PM
To: Eilbacher, Jane C. (CMS/CMMI)
Subject: Re: Response to Request for Information: Evolution of ACO Initiatives at CMS

Here are my full answers. Thanks for your email and I hope this helps.

What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?

In our small rural community there is only one primary care physician for the hospital and clinic. For more than 30 years my primary care has been provided by nurse practitioners. I travel hundreds of miles to see 4 different specialists. My situation is typical for this community. As a Medicare patient I was assigned to this area but many who live here were not. Community health systems that provide more than 50% of the primary care for a given zip code should be assigned all of the beneficiaries in that zip code.

What are the most critical design features of a provider-led community ACO model and why?

To better facilitate care for it's members the community ACO should agree to act as the Medical Home for its community, coordinate care outside the community and provide comprehensive support for patients with chronic diseases. This will provide the highest level of care for the community, lower costs and enhance patient satisfaction. Community ACO's should receive a $10 per member per month payment to finance these additional services.

What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area?

Pediatric measures, generic drug utilization and ED utilization measures should be added.

Are there models to consider that better integrate community-based services beyond the traditional medical system?

The Patient Centered Medical Home integrates community-based services, but does not pay for them. Community ACO's should be required to share up to 10% of the $10 PMPM payment and shared savings with community resources that agree to provide social support, food, transportation and/or behavioral and mental health services for the most vulnerable patients.

Andrew Wickman

I. Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

a) Yes.

b) As more organizations gain experience managing care in private ACOs, MSSP and other risk-based contracts, there will be a larger pool of potential participants who may be interested in Pioneer's model of greater risk delegation.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

a) Accept all organizations that meet the qualifying criteria

b) With adequate screening in the application process, it is unnecessary to limit the number of participants. The primary advantage of removing participation limits is that more organizations will participate, increasing the number of Medicare beneficiaries with access to care through an ACO. That said, programs with limited participation do confer more "clout" to selected participants; without limits, participating organizations' brands will receive less of a boost as a result of being included in the program.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

a) Revising the benchmarking process is one of the most critical refinements needed to increase participation.

B. Population based payments.

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

a) Yes

b) Health systems may use different approaches to deploy care management efforts and may receive different amounts of revenue from inpatient and outpatient care and therefore will be comfortable with different levels of risk in each category.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

a) No comment

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

a) Yes

b) Demonstrating adequate financial reserves will protect against insolvency while still allowing organizations to transition to PBPs earlier in the program.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

a) No comment

II. Evolution of the ACO Model

A. Transition to greater insurance risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

a) Yes

b) Capitation provides significantly more flexibility in deploying resources to benefit patients. Creating an ACO requires making substantial investments far before shared savings payments are received. Capitated payments could help avoid significant cash flow problems.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

    a) Organizations should have the option to take insurance risk for all categories of spending, but should not be required to take risk on all categories. For Medicare-Medicaid beneficiaries, however, ACOs should take risk for both Medicare and Medicaid.

3. Are there services that should be carved out of ACO capitation? Why?

    a) Out-of-area, transplant and specialty pharmacy should be carved out of capitation as a default. Given the importance of behavioral health to treating other medical conditions, ACOs should have the option to include behavioral health.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

    a) ACOs would need to contract with non-ACO providers to establish rates. ACOs should also have the opportunity to create subcapitation agreements with other providers that are well-equipped to well manage specific populations or types of care.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would not be appropriate for ACOs assuming full insurance risk?

    a) Regulatory components of the Medicare Advantage framework that should be adopted for ACOs include RAD audits of risk coding, continued quality measurement (ideally aligned with STARS quality measurement) and utilization metrics review to ensure ACOs are not limiting utilization.

    b) As reflected in the Medicare Advantage compliance framework, ACOs should also:

(1) Have the ACO's compliance official report directly to the ACO's governing body but not be the ACO's legal counsel

(2) Establish appropriate mechanisms to anonymously report compliance problems and ensure all ACO employees, participants and contracts understand how to communicate compliance issues

(3) Incorporate compliance standards into contracts for ACO providers / suppliers and service level agreements

(4) Provide compliance training for the ACO, its participants and its providers / suppliers

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

a) Complying with any applicable state licensing requirements imposes a large administrative burden on ACOs. To the extent possible, government regulations, reporting requirements for quality and safety programs, and state licensure restrictions should be standardized to promote greater uniformity and lower compliance expenses.

b) Waivers for Civil Monetary Penalties, Anti-Kickback, Stark Law, ACO pre-participation, ACO participation, Shared savings distribution, and Patient Incentives should be continued.

c) In addition, ACOs should continue to have the flexibility to specify their preferred method for repaying potential losses, and how the method would apply to the ACO participants and ACO providers/suppliers without implicating fraud and abuse laws.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

a) ACOs would need significant new infrastructure, including network management, contracting, member services, claims processing, and data analytics among other capabilities. Core contracting and claims processing services could be obtained from TPAs.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking.

a) The rate-setting process should be more transparent and participatory. CMS should allow for review and comment on actuarial assumptions, and provide a mechanism for an independent review of the process and data used to establish the resulting rates.

b) In addition, capitation benchmarks should be based on a risk-adjusted market rate, rather than the ACO's own previous utilization. One of the primary issues with the Pioneer model is the methodology for setting the benchmark. Setting the benchmark based on an organization's previous utilization rather than risk-adjusted market averages can distort incentives. For example, organizations that have a track record of excellent population health management are likely to have low utilization and therefore a very low benchmark. It will be difficult for such an organization to accrue significant savings under the Pioneer model, because the levels of waste in the system are low. Although this type of organization is performing better than market comparators, its contribution to the Triple Aim will not be rewarded through Pioneer. Conversely, organizations with high levels of utilization and "waste" can make small changes to rein in spending and accrue significant savings, even if they are still outspending comparable organizations. A better approach to benchmarking would reward not only improvement, but also absolute performance. While ACOs should still be incentivized to lower utilization relative to a benchmark, they should also be incentivized for starting with high quality care at low utilization levels.

c) Regardless of the benchmarking approach used, the capitated payment should be adjusted in the first year

based on accurate HCC coding to avoid significant financial losses for the ACOs.

8A. What are the advantages and disadvantages of using national expenditure growth trends?

d) National benchmarks have the potential to increase pressure to reduce spend in high cost areas. However, they also reward or disadvantage ACOs based on market factors unrelated to their performance.

8B. What about for using a local reference expenditure growth trend instead?

e) Using local growth trends would avoid disadvantaging or benefitting ACOs based on market influences on growth trend outside their control. Quality of care varies from community to community and it is important to allow for regional differences.

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

a) The best approach to risk adjustment would be MA HCC coding. Although HCC coding has its own issues, it would create consistency and is preferable to other approaches, like demographic risk adjustment which does not adequately account for clinical risk.

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

a) Benefit enhancements like lower co-pays are important for delivering high quality care, because patients often face financial barriers to the care required to prevent exacerbations and complications.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

    a) No comment

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

    a) Appropriate risk adjustment, benchmarking and trend growth reduce the threat of issues related to adverse selection.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

    a) Yes

    b) Allowing patients to voluntarily align may increase their engagement with their ACO care team. However, patient-driven alignment could expose providers to the risk of having attributed patients for whom they have not provided a significant amount of care.

B. Integrating accountability for Medicare Part D expenditures

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an

ACO program to help ACOs and sponsors mitigate or avoid these barriers?

a) No comment

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

a) Yes

b) Managing pharmacy utilization is an integral part of patient care and some ACOs may be well-positioned to manage and take risk for this portion of spend.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

a) No

b) ACOs would need access to Part D data if accepting full risk. Also, ACOs would also need to build or contract for pharmacy benefits management capabilities.

C. Integrating accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

a) ACOs should have the option to assume accountability for Medicaid as well; many organizations are already exploring opportunities to manage Medicaid patients through state-based programs.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO

be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

a) CMS should prioritize Medicare-Medicaid beneficiaries, because of their relatively high need, which presents an opportunity for the most significant improvements.

b) However, CMS should provide the option to include all Medicaid populations; some systems are developing innovative programs with a focus on children, healthy adults, and other populations.

c) ACOs should be responsible for their attributed patients, rather than all beneficiaries in a geographic area. Making ACOs responsible for all beneficiaries in a geography would significantly increase the risk for the provider. It would place a significant burden on the provider to engage hard-to-reach beneficiaries – although this is an important goal for providers to pursue, it is overly onerous to place ACOs at risk for this group.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

a) States should seek to align existing population care management efforts with ACO models to minimize areas of conflicting or overlapping services.

b) Given State budgetary constraints, States may also need support from CMS to support an ACO initiative.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

a) Many organizations are early in the process of creating an enterprise data warehouse and population data analytics tool with the capabilities to integrate data, although these technologies are emerging and there is significant variation between ACOs.

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

a) CMS should mandate that the state pay the ACO a capitated payment on top of Medicare's capitated payment for Duals. Today, ACOs may receive capitated payments from Medicare and FFS payments from Medicaid, which increases complexity and skews incentives.

D. Other approaches for increasing accountability

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

a) This geographically-based model would present significant challenges to ACOs, assuming there are no mechanisms to influence where a beneficiary seeks care – this type of model would present significant risks to the ACO.

b) However, using an attribution model based on historical care patterns creates the possibility that some beneficiaries will "fall through the cracks" (e.g., an

individual who only visits the ED). A geographic-based model would allow all these individuals to be engaged.

c) To capture unattributed Medicaid beneficiaries without using geographic attribution, marketing/outreach efforts could be used to encourage unattributed beneficiaries to visit a PCP that is affiliated with an ACO. This approach could increase the influence of a provider-led ACO without putting the ACO at risk for non-attributed beneficiaries. Alternately, the types of visits considered for attribution could be expanded to include non-traditional sites of care such as urgent care or retail clinics, assuming those sites of care had an ACO partner that would accept their attributed patients.

d) Regardless of attribution approach, it could be beneficial to integrate community-based services. Many ACOs provide additional services such as case work, social work and health coaching without reimbursement.

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

a) Yes (service delivery and payment reform initiatives combined)

b) Yes (primary care within ACO and/or ACO with episode based payments)

E. Multi-payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

a) CMS ACOs models have already been extremely influential in creating private payer ACOs. CMS can continue to act as a convener for organizations, as it has done through CPCI.

b) CMS should continue offering models that encourage broad participation. However, CMS should analyze requirements to transition a portion of contracts to risk, because it may be too constraining for providers in markets dominated by a single private payer.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

a) CMS should work to align national, state, and local reporting for quality/safety programs and licensure restrictions to those proposed under the National Strategy for Quality Improvement in Health Care. CMS should align STARS and ACO quality reporting.

A Proposal for the

Center for Medicare and Medicaid Innovation

Request for Information:

Evolution of ACO Initiatives at CMS

Date
February 28, 2014

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Section I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. Second Request for Applications for the Pioneer ACO Model

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

Yes, we believe there would be interest and that CMMI would receive new Pioneer ACO applicants if the Pioneer model was made available once again. However, in doing so, CMMI should consider its objectives. If CMMI believes it requires additional Pioneer ACO experience to test the current design elements, then accepting new Pioneer applicants under the current program will meet this objective. However, if CMMI desires to significantly increase the enrollment in this program, then current design elements could be changed to maximize this objective. Further discussion as follows:

Why would organizations apply under the current Pioneer program?

- The current program has been in existence for two plus years and the market is familiar with the program
- CMMI's collaborative approach working with the Pioneer ACOs has been a positive experience. CMMI's willingness to work with its ACO partners should instill confidence with the program and new ACO applicants
- Many of the design elements have been reviewed and, where necessary, modified to enhance the program's overall objectives
- The following Pioneer program features are viewed very positively by the market:
  - **Prospective attribution**. Prospective attribution enables ACOs to focus on a specified list of beneficiaries over the entire performance year. This methodology supports better quality and cost efficiency outcomes for ACO beneficiaries
  - **Baseline**. The baseline reflects the actual ACO beneficiaries' claims cost
  - **Decedent adjustment**. Reflecting the decedent adjustment in the shared savings calculation minimizes the impact of potential different underlying mortality rates
  - **Reporting**. The Pioneer ACO reporting package continues to evolve based on the collaborative efforts from CMMI and its Pioneer ACO partners
  - **Open communications**. The CMMI Pioneer ACO staff provides thoughtful responses to the ACO's questions and also makes itself readily available to the Pioneer ACOs when additional discussions are necessary
  - **Excess loss**. This feature provides protection to the ACOs from excessive high cost beneficiaries, at no direct expense to the ACO
- Participate in the testing and shaping of design features that are important to the future of the program, such as:
  - Transition to capitation and partial capitation with safeguards and protections
  - Patient engagement and enhanced benefits
  - Special population focus such as frail elderly, institutionalized, poly-chronic, etc.

  - New methods for measuring performance using more timely metrics and/or relating directly to specific interventions
  - Long-term sustainability and differentiation of the ACO, Medicare Advantage and traditional Medicare programs

Why would organizations not apply under the current Pioneer program?

- Insurance risk of the program may be seen as too large given the shared savings opportunity
- Costs of operations and compliance may be seen as cost prohibitive given the shared savings opportunity and the long lead times until gain share payments are distributed.
- Program continues to evolve, thus unable to clearly define its long-term strategic direction and sustainability, including full or partial insurance risk features
- Complexity and transparency limitations of the shared savings calculations, including challenges with:
  - Decedents
  - Baseline projection/discounting methodology
  - National and local/regional trends, comparison populations
  - Inclusion of managed populations in the national reference experience
  - Risk scoring or other morbidity propensity scoring
  - Quality measures and development of quality measure targets
- Open network for beneficiaries. Ability to impact acute admits at out-of-system facilities due to lack of real-time data
- Inability to impact care-seeking behavior via benefits and steerage
- Claims data challenges:
  - Timeliness. Pioneer ACOs currently receive beneficiary data one-month into the performance year at which time they can then begin to analyze the data. This is a significant portion of the performance year in which ACOs have little-to-no information with which to improve its beneficiaries health
  - Unavailability of certain ACO data:
    - Opt-out beneficiary data
    - Substance abuse data which is a key co-morbidity for care management outreach
  - Data elements might be seen as less than comprehensive and/or not consistent with market definitions or expectations; example, through-date methodology shifts the accountability period and thus is not consistent with typical health care definitions
- Transparency and data limitations might be seen as less than optimal analytics and reporting support services given the level of insurance risk inherent with the program

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

It is our opinion that CMS should accept all organizations that meet pre-defined qualifying criteria. It is critical that the pre-defined criteria reflects those requirements that align with the objectives of the program such as experience with risk contracts, care management activities, and quality outcomes measurements.

What are the advantages/disadvantages for accepting all organizations that meet the pre-defined qualifying criteria?

Advantages include increasing the number of organizations, provider participants and beneficiaries which will support the pursuit of obtaining the Triple Aim. In addition to providing accountable care for the ACO Medicare beneficiaries, there will be a spill-over effect to non-ACO beneficiaries in that provider participants will likely transition to providing care to their entire panel using a single set of care management and administrative processes.

Another advantage for accepting all willing and able organizations is that this will increase the number of organizations and health care leaders working together to improve the Medicare ACO model. A larger number of participants will lead to stronger evidence and support, as well as data credibility, in developing evidence-based medicine guidelines and measuring the effectiveness of quality metrics for Medicare beneficiaries. It will also aid in and accelerate the development of additional performance and quality-based measures related to the improved care of Medicare beneficiaries.

We believe the disadvantages are limited. However, one potential disadvantage for accepting all organizations is it could limit the number of future organizations for testing either new programs or new program features such as Part D coordination, extension of program to include Medicaid and CHIP beneficiaries.

Other Considerations—There are essentially two possibilities for the Pioneer program with regards to the existing original Pioneer program participants who began January 1, 2012:

1. Existing Pioneer ACOs remain in the current five-year program, which either terminates or extends beyond 2016, or
2. Existing Pioneer ACOs all move to the new Pioneer ACO program

Considerations for developing policy for the existing Pioneer ACO program should include:

1. Advantages and disadvantages to existing Pioneer ACOs under the new program, versus the current (savings model, attribution, supplemental benefits, etc.)
2. Quality reporting: Will existing Pioneer ACOs be held to a higher standard than first year Pioneers under the new program? Or will new Pioneer ACOs be held to the higher standard of the existing Pioneer ACOs, i.e., first year quality score will not be based on the ability to report on the quality metrics

Regardless, CMS should clearly articulate the long term trajectory for Pioneer ACOs that assures they have a sustainable model. This should include CMS' vision for transforming Medicare with ongoing roles for Medicare Advantage and ACOs as alternatives are provided to traditional Medicare fee-for-service.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

We recommend the following additional refinements:

- Increase shared savings percentages by at least 10 percent to providers and reduce CMS share to offset high administrative costs (provide risk/reward balance)
- Set quality score targets based on Medicare FFS experience
- Work with industry stakeholders to establish a common set of quality measures and reporting methodology
- Consider capitation or partial capitation if CMMI delegates accountability and responsibility to qualifying health care organizations and gives these organizations the ability to manage their attributed population in real time
- Make certain that CMMI has the clear authority to correct any unintended consequences (AWI, negative national trend, etc.)
- Simplify EHR requirement or eliminate double score
- Simplify FQHC assignment
- Provide the ACO access to its beneficiaries claims data unless the beneficiary opt-outs, at which time the ACO will be required to stop all reporting, care management or other activities using the claims data
- Allow an ACO the decision to exclude opt-out beneficiaries from the ACO program
- Provide real-time/near-time access to acute inpatient authorizations, eligibility pings or other point-of-service data information
- Allow steerage through participating provider referrals or benefit redesign/enhancements
- Allow ACOs more direct access to engage beneficiaries in their own health and wellness
- Allow ACOs the option to either take stop loss through CMS or to manage and retain the risk on these high cost patients
- Allow audits to be performed by CMS or third party vendors and shared with the ACOs to verify the data and calculations for accuracy. Any auditor would need to adhere to strict standards regarding beneficiary confidentiality and PHI requirements

B. Population-Based Payments

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

Allowing the flexibility to have varying reductions among Part A and Part B services is a more attractive option than currently offered. This change could allow certain ACOs, such as a comprehensive clinically integrated provider group, to participate in population-based payments (PBP) at an accelerated rate. In addition the ability to choose different FFS reduction amounts is appropriate for organizations as they develop the capabilities required

to administer payments to providers. This includes claim operations, claims payments, and incentive program development.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

Yes, allowing suppliers of DME equipment to be included on the list of participating providers that receive reduced FFS payments can align with an ACO's population management strategy. By CMS allowing this, the ACO can apply the reduced payment across all of its providers, thus incentivizing the providers to work together for providing continuity of care for their beneficiaries. We recommend this philosophy to include any service provider, not only DME, with which the ACO is willing and has the ability to enter into a value-based incentive contract.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

Yes. If an organization has the ability and capital to assume risk their decision to do so should not be limited based on prior year performance, but rather by their ability to capitalize the risk. We recommend CMMI work with the NAIC to develop recommendations about risk-based capital requirements for organizations that accept PBPs. We believe any capital requirements should be carefully considered and should seek to balance capital requirements with any undue burdens.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

Assuming the goal of the program is to encourage ACOs to move to PBPs and away from fee-for-service reimbursement, we recommend changing the current Pioneer ACO PBP policy. The withhold under the current methodology means an ACO would need to have a *minimum* 10 percent gross savings in the year they move to a PBP to break even, relative to the shared savings tracks Core and Option A and even greater savings for Option B. The breakeven point for an ACO is lower as the quality score decreases; however, offsetting this decrease is the proportion of expenditures for the ACOs providers/suppliers.

The table below illustrates the net savings for an ACO based on Pioneer track, gross savings, and quality score. This table serves to provide an understanding of when a particular track becomes attractive to an ACO, assuming savings in a performance year. As the table illustrates, Alternative 1 and Alternative 2 Net (ACO) Savings amounts are equal or greater than Core, Option A and Option B in all 15 percent and 10 percent scenarios. Further, the table shows that using the 5 percent Gross Savings scenarios results in greater savings under the Core, Option A and Option B.

Quality Score	Gross Savings	Net (ACO) Savings				
		Core	Option A	Option B	Alternative 1[1]	Alternative 2[2]
100%	5%	3.5%	3.5%	3.8%	2.9%	2.0%
	10%	7.0%	7.0%	7.5%	7.0%	7.0%
	15%	10.5%	10.5%	11.3%	11.1%	12.0%
75%	5%	2.6%	2.6%	2.8%	2.1%	1.3%
	10%	5.3%	5.3%	5.6%	5.7%	6.3%
	15%	7.9%	7.9%	8.4%	9.2%	11.3%
50%	5%	1.8%	1.8%	1.9%	1.3%	0.5%
	10%	3.5%	3.5%	3.8%	4.3%	5.5%
	15%	5.3%	5.3%	5.6%	7.4%	10.5%

[1]Assumes 100% of Part B expenditures are ACOs providers/suppliers and that Part B is 40% of total Part A/B expenditures

[2]Assumes 100% of expenditures are ACOs providers/suppliers

We recommend CMMI consider the incentives and disincentives for Pioneer ACOs when modifying current or developing new shared savings track features.

Section II: Evolution of the ACO Model

A. Transition to Greater Insurance Risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

Yes, CMS should offer capitation with insurance risk to those ACOs that have the desire, capability and appropriate licensure to manage risk. However to maintain broad participation CMS will need to offer multiple models. While larger, experienced provider entities will be able to mange the financial and administrative requirements associated with full insurance risk (i.e., capitation), there are probably just as many providers, if not more, that are not ready and may never wish to participate in capitation arrangements and obtain the required infrastructure to pay other providers. For example, small physician-sponsored organizations consisting of primary care practices and small Federally Qualified Health Centers may not wish to be capitated. Therefore, we believe it is important to build in the flexibility to allow for a range of options from limited to full risk to accommodate the diversity of ACOs.

Potential benefits:

- Enhanced services, lower costs and higher quality outcomes for beneficiaries
- Increased patient engagement with enhanced benefits
- Enhanced ability for ACOs to manage population health and assume full responsibility for results
- Provide flexibility to move to aligned value-based provider and supplier reimbursement models
- Provide range of options including partial capitation for select services for which ACO has authority and capability to assume insurance risk
- Contribute to long-term objective for ACOs to participate in Medicare program as an alternative to Medicare Advantage and traditional Medicare

Risks considerations:

- Beneficiaries must not be denied access to needed services or providers
- Process for setting capitation rates must be fair, consistent and transparent
- Organizations accepting risk must have the financial resources and reinsurance coverage to protect beneficiaries and withstand losses
- Organizations must provide the appropriate administrative functions. The list below, although not meant to be comprehensive, should serve as a high-level list of potential services that might be required if an organization assumes full capitation.
  - Network management (i.e., credentialing, contracting, network adequacy)
  - Claims processing and provider reimbursement (i.e., payment integrity, provider disputes, capitation development and payment)
  - Member services (i.e., eligibility, communications, call centers, disputes, risk stratification)

- Financial risk management (e.g., reserves, reinsurance, projections, reconciliations, risk scoring, statutory and capital surplus)
- Clinical and quality capabilities including case management/disease management/utilization management/HEDIS and STARs reporting
- Additional legal services
- Additional accounting services

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

Accountable care encompasses the entire spectrum of health care and, therefore, we believe that all spending categories provided under Medicare should be offered and ACOs should have the flexibility to select based on individual objectives. We defer to Section C below for a discussion on Medicaid financial risk transfer to the ACOs.

3. Are there services that should be carved out of ACO capitation? Why?

ACOs should have the flexibility to carve out services that their participating providers cannot provide or that the ACO is unable to influence or control such as out-of-area emergency room visits, transplants, emergency transportation, new technologies, Part D claims, etc.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

ACOs will need to be assured that services provided by non-ACO providers can be reimbursed at traditional Medicare rates, unless other contract reimbursements are agreed upon by the ACO and non-ACO provider. The actual payment to these providers could be administered by the ACO or by CMS, at the provider's choice. If CMS administers the payment, then there would likely need to be a negative offset to a future capitation payment to reflect these reimbursements.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would not be appropriate for ACOs assuming full insurance risk?

The following elements should be considered if ACOs are afforded the opportunity to assume full insurance risk. Note that beyond the capital adequacy requirement, we cannot provide a recommendation since the detailed features of a program would need to be considered before recommending if any of the below elements are applicable.

- Capital adequacy requirement to withstand unexpected increased liability amounts
- Provider network adequacy requirements to ensure services are available to beneficiaries. This compliance requirement is only applicable if an ACO is allowed to restrict its network of providers for its beneficiaries. If provider network restrictions are not allowed, consistent with the current program, then this requirement is not applicable.
- Evaluation and potential consolidation of the ACO quality performance measures and STARS measures
- Customer service requirements (e.g., member grievance support)
- Risk adjustment and EDS/RAPS data submission

- Marketing and other operational requirements
- Administrative expense transparency (and, don't forget the insurer fee because they would count)
- Similar bid submission process to support revenue requirement and comparable savings threshold
- Financial performance and minimum loss requirements, assumes that there is a bid submission process

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

Many ACOs would likely not currently have the capital to meet state licensure requirements without receiving a capital infusion, nor will many of them have the financial wherewithal to develop the administrative infrastructure needed to achieve and maintain compliance with additional federal and state regulatory frameworks. Thus from a pure beneficiary growth perspective, these requirements are not optimal. Further, extending requirements for administrative infrastructure to ACOs ultimately draws dollars away from service delivery and quality improvement. Therefore, we suggest CMS consider how ACOs can leverage existing administrative infrastructure or join together to use shared administrative management infrastructure without violating anti-trust statutes to acquire low cost scalable solutions.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

The list below, although not meant to be comprehensive, should serve as a high-level list of potential services that might be required if an organization assumes full capitation:

- Network management (i.e., credentialing, contracting, network adequacy)
- Claims processing and provider reimbursement (i.e., payment integrity, provider disputes, capitation development and payment)
- Member services (i.e., eligibility, communications, call centers, disputes, risk stratification)
- Financial risk management (e.g. reserves, reinsurance, projections, reconciliations, risk scoring, statutory and capital surplus)
- Clinical and quality capabilities including case management/disease management/utilization management/HEDIS and STARs reporting
- Legal services
- Accounting services

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

Capitation rates can be set using multiple approaches. The most common relies on defining a set of covered services and using assumptions regarding beneficiary cost sharing, utilization rates, and unit cost reimbursements. The assumptions can be based on historical

experience, trended to a projection period with or without other adjustments to reflect differences in populations and risks, risk selection, pent-up demand, reduction for excessive utilizations, etc. Sometimes capitations are developed replacing the trended historic utilization rates with target benchmarks, e.g. 25th percentile. This approach is used if the historic utilization rates are considered to be inappropriate.

Advantages and disadvantages for using National Expenditure Growth Trends per the Pioneer methodology.

Advantages include:

- When national trends are increasing, this helps reduce the variation in average overall per capita costs. The high cost geographies benchmark is mitigated, while the low cost geographies benchmark is slightly increased, all else being equal.
- Trend and National component of increase is reflective of a National credible data set
- Trend percentage is applied to the local ACO cost structure and thus reflects a portion of the local costs

Disadvantages:

- When national trends are decreasing, the reduction variation goal (i.e., rewarding low cost geographies and penalizing high cost geographies) is not met. In fact, the calculation results in penalizing both the low and high cost geographies, with the low cost geographies being adversely penalized vs. the high cost geographies
- National trend may not be representative of local trends, including change in wages, utilization mix, natural disasters, weather, epidemics, etc.
- Policy changes that impact regions differently (GPCI, AWI, etc.) are not accounted for when using national expenditure growth
- Under the current Pioneer ACO model, the national reference expenditure includes beneficiaries who are aligned to ACOs, i.e., beneficiaries who are being managed. The managed beneficiaries are assumed to have lower trends than the unmanaged cohort and therefore the national expenditure growth trends are inherently lower than they otherwise would be for a population/cohort that is entirely unmanaged

9. What are the advantages or disadvantages of different strategies for risk-adjustment?

Measuring the impact of programs and interventions, particularly on a longitudinal basis, can be challenging. The key to appropriate measurement is the setting of meaningful targets and adjustments for individual and population changes related to risk and case mix. The pre-post methodology currently utilized for target setting and retrospective reconciliation is challenged by some of the same issues that the disease management industry has dealt with over the last ten years. Given the absence of a control population, for matched control analyses or difference-in-difference calculations, the pre-post design can be helpful, but only if risk and other variables are handled accordingly.

We recommend risk adjustment methodologies that are based on an underlying episode of care framework as the core risk adjustment methodology. Whether used prospectively to identify individuals for medical management interventions, or retrospectively to adjust for risk differences in measurement, the linkage between risk and episodes removes some of the challenges associated with the HCC methodology and creates a stronger linkage between

performance improvement against risk adjusted cost targets, with the ability to identify what underlying components changed in order to meet the financial objectives.

As Al Lewis, one of the leading care management outcomes analysts in the country, notes in various publications, one also needs to have “plausibility indicators” (e.g., utilization measures, functional outcome changes, e.g., SF-12 or 36, quality improvement etc.) in order to support the notion that a financial target was successfully met. Without these indicators, one really never knows whether an ACO actually changed their internal processes to become more efficient or whether inherent biases in the data or measurement were randomly in its favor.

Although we are confident that CMS has done a tremendous amount of sensitivity testing on the pre-post methodology, below we highlight critical variables that can highly influence the overall target setting and retrospective analyses, and should be considered when applying risk adjustment methodologies:

1) Outlier Handling—Cost outliers in the baseline and measurement period need to be investigated. Various thresholds for outliers need to be considered such as:
    a. Outlier inclusion
    b. Capping or removing outliers based on a limit:
        i. Stop loss threshold
        ii. Dollar cap (e.g., $100k)
        iii. Percentile cap (e.g., 97.5%)
    c. Consideration for setting thresholds separately for baseline and measurement periods based on different cost distributions in each period
    d. Potential trend adjustments should be considered to project baseline to performance period, dependent upon approach and methodology (e.g., stop-loss)
2) Change in Risk—there is no perfect way to address for changes in the population over time. Risk adjusting total expenditures can be helpful in setting targets, but risk scores may not fully account for population characteristics, particularly when the baseline population and the measurement period population are substantially different. If this is the case, then a target based on a substantially different baseline population may not provide a meaningful comparison to observe the impact of the ACO.
3) Use of Cohorts—Depending upon the size of the population, CMS might consider basing its measurement on multiple cohorts of individuals to provide more consistency in the population comparison over time.
4) Attribution—Similar to the issue of “requalification” in the disease management industry, the same population definitions must be applied equally to the baseline and measurement periods. If there are any meaningful differences in the approach for defining those periods, the overall comparison can be biased in either a positive or negative direction.
5) Change in Case Mix—Depending upon the prevalence of various conditions, one might consider reweighting the baseline and measurement period sub-PMPMs to closely reflect key sub-distributions around chronic conditions, etc. (e.g., if there are many more heart failure patients in the measurement period than in the baseline period, the measurement period will be more expensive and this effect needs to be

neutralized. In extreme cases, risk adjustment alone is insufficient in accounting for these differences).

Clinical Exclusions—Some clinical areas (e.g., transplants, ESRD, AIDS) are so catastrophic that ACOs should have the choice of managing these high cost groups or having them removed from the measurement methodology.

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

An ACO should be able to provide benefit enhancements (Parts A, B and D) to its beneficiaries with the objective that these enhancements will result in better quality and improved total population health. These could reflect:

- Reduction in beneficiary cost share amounts when beneficiaries receive services at the ACO's preferred providers
- Reduction in beneficiary cost share amounts when beneficiaries enroll in care management programs
- Reduction in beneficiary cost share amounts when beneficiaries are identified with certain diagnoses or have certain diseases, for example, elimination or reduction in beneficiary cost share for medications needed to treat chronic diseases
- Adding use of connected technologies such as smart phone apps, telehealth, e-consults, and other innovative technologies to improve access, quality and efficiency
- Adding non-Medicare covered benefits, i.e., waiving three-day inpatient stay for SNF, increased transportation services, and dental
- Piloting new practices such as testing innovative gamification approaches of appropriate medical services

Note that benefit enhancements would be most impactful with Medicare beneficiaries and least impactful with Medicaid since there is little or no beneficiary cost share in this program.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

ACOs will have to successfully address a number of issues as they transition to insurance risk:

- Capability to manage risk and potential provider contracts. Are the participating providers committed to and capable of accepting risk?
- An ACO will need to adhere to administering a payment integrity program for appropriate payments, identification of any fraud, waste or abuse claims, reconciliations and likely for encounter submission data to CMS
- Capability to successfully manage member services
- Infrastructure to manage risk including medical management, financial and actuarial, data management, reserves and reinsurance
- Appropriate licensure to accept and manage risk and comply with state and federal requirements
- Financial capacity to accept risk and withstand a period of losses

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

ACOs should have to follow the same rules that Medicare Advantages plans are required to follow. It will be important to develop a sound methodology to project an ACO's capitation and/or provide retrospective morbidity and mortality reconciliations and/or adjustments to ensure the capitation was appropriate.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

Beneficiaries should be allowed to elect alignment to an ACO.

Advantages include

- The commitment of the beneficiary should solidify their relationship with the ACO and thus likely support an engaged beneficiary
- Increases the ACO's number of beneficiaries that provides credibility to results and reduces unwanted variation (e.g., law of large numbers)
- Supports the ACO's growth initiatives while reducing the ACO's unit cost of fixed administration
- Provides the ACO confidence in knowing who their aligned beneficiaries are across performance years, which in turn improves the stability of an ACO's population across performance years

Disadvantages include:

- Potential marketing tactics that might be unwanted, unlawful or outside of CMS policy for marketing to beneficiaries
- Beneficiary cannot elect non-alignment, unless the beneficiary meets pre-defined criteria
- Ability of the ACO to manage the care of a beneficiary if the majority of their services are from non-ACO providers

B. Integrating Accountability for Medicare Part D Expenditures

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

Currently, Part D is not part of the shared savings calculation and ACOs only receive a proportion of the ACO's beneficiaries' drug claims, specifically ACOs only receive a beneficiary's out-of-pocket cost share amount for only the beneficiaries that are enrolled in a PDP. Given these contributing factors, Part D claims typically are not actively managed by the ACO.

CMS could encourage collaboration between ACOs and Part D Sponsors by taking one of the following increasingly complex forms:

1. Include Part D drug claims in the savings calculations. Additional considerations for this option include:
    a. Approach provides greater incentives for ACOs to collaborate with Part D plans because ACOs would have "skin in the game" around the management of pharmacy costs for beneficiaries attributed to them
    b. Potentially reduces any "Rx claim arbitrage" that might be occurring through the shifting of Part A or Part B pharmacy claims into Part D to avoid their inclusion (currently) in ACO Part A/B medical claim payments and contribute to savings calculations
    c. Encourages a total health view of a patient in managing their total health experience and total health expenditures in a holistic rather than somewhat fragmented manner
    d. Encourages use of less costly generic prescriptions and mail order services, which in turn should reduce a beneficiary's out-of-pocket cost share while increasing the beneficiary's compliance for drug adherence. These outcomes should ultimately contribute to reductions in beneficiaries' total medical and pharmacy expenses.
    e. Enablement of more efficient clinical intervention and care based on timely sharing of Part D sponsor prescription claim data with the ACO. This collaboration could contribute to identification of early warnings for emerging risk factors among an ACOs attributed beneficiaries, thus potentially avoiding increasing medical expenses. This would require contractual data-sharing agreements and operational data-sharing procedures between Part D sponsors and ACOs. This could be cumbersome for ACOs administratively depending on the number of Part D plans operating in their geography.
2. Include Part D payments into the Population-Based Payments (PBPs). Additional considerations for this option include:
    a. Option might include a provision that the ACO beneficiaries only use a specific PDP plan that is specifically designed to be offered only to the ACO beneficiaries. In addition to the added costs for PDP plans to develop these options, which would likely require a CMS waiver to offer this plan, there exists the likelihood that Medicare beneficiaries would require specific marketing materials. These materials, as with all PDP plan beneficiary materials, would need to be approved by CMS. Additionally, this offering might be considered as "marketing" for the ACO. This would need to be carefully considered in the

context of the long term positioning of MAPD plans and the ACO program. Lastly, providing another clearly defined option, which would be required under this scenario, to Medicare beneficiaries for their medical coverage might be considered less attractive to the Medicare program overall.

b. Increases collaboration between Part D sponsors and ACOs by requiring contractual agreements to exist to govern the sharing of the PBPs, if the ACO receives the PBPs, but the Part D sponsor holds the claim liabilities (reimbursement of which would be reduced under the proposed PDP structure).
c. Pharmacies would not need to be involved in the PBP agreements if the Part D sponsor still contracts with the pharmacies on a traditional FFS basis. Or, the Part D sponsors could choose to change their contractual structures with network pharmacies and begin including partial PDP sharing with them (based on the PDP sharing they receive from the ACOs) as well as the reduction in FFS claim reimbursements they would receive from CMS.
d. This approach requires significant administrative structures to be built between the Part D sponsors and ACOs (primarily at the ACOs). This will be most burdensome on the ACOs since Part D sponsors (and PBMs) and pharmacies often have administrative structures in place to handle various payment streams. Thus we recommend minimizing any new layers concerning legal and administrative requirements by leveraging the current contracts among Part D plans, PBMs and pharmacies.

Each of these options would incent the ACOs to significantly increase their collaboration with Part D Sponsors.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

These topics have been addressed in other areas of the response.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

ACOs do not currently have enough information to accept full risk for Part D expenditures. The current Part D data provided to Pioneer ACOs only contains claims for those beneficiaries who are enrolled in a PDP. This means Pioneer ACOs have no drug utilization information for a significant portion of their population. In order for a Pioneer ACO to accept full risk for prescription drugs it is imperative that they receive full claims detail for all beneficiaries with prescription drug coverage.

Timeliness of information is important when considering the impact an ACO and their providers can have on its beneficiaries. E-prescription notification to the ACO (not just the prescribing provider) will greatly enhance the ability of the ACO to provide outreach and avoid costly ER visits and inpatient admissions due to adverse drug interactions.

In addition, those beneficiaries with drug coverage are covered under numerous different prescription drug plans, each with their own formularies, cost sharing, incentives, etc. The ability of a Pioneer ACO to manage prescription drug costs is dependent on gaining access

to this information in order to understand how best to manage the costs of their aligned beneficiaries.

Pioneer ACO providers have the ability to improve patient quality and manage costs by integrating Part D pharmacy information with clinical information from Parts A and B. For example, polypharmacy, drug-drug interactions and compliance can be managed and patient and program costs can be reduced by prescribing lower-cost (e.g. generic) drugs. Without access to information to help support the cost-reduction effort it would be difficult to expect an ACO to accept full risk for Part D.

C. Integrating Accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

States are actively exploring many ways to contract directly with providers willing to align payments with results, including cost reductions and quality improvements. Accountable provider based care agreements exist within both Medicaid capitated managed care and fee-for-service arrangements. Minnesota's Department of Health and Human Services' Integrated Health Partnerships (a.k.a. Health Care Delivery System) demonstration project, for example, offers both gain-sharing and risk-based models through direct contracts with eligible providers interested in driving down cost and improving quality.

States, and the providers who traditionally serve Medicaid enrollees, recognize the many benefits of multi-payer collaboration in structuring and administering more standardized accountable-based care arrangements. Many providers would willingly extend their agreements to include patients covered by Medicare, assuming relative consistency between payer contract provisions. However, providers may have concerns about enrolling people who are dually eligible. Until financial misalignments between Medicare and Medicaid are resolved at higher policy levels, the complexities of determining gain-sharing payment responsibilities for dually eligible enrollees is daunting enough for insurers—many providers may not have the fortitude or infrastructure needed to wade through these complexities, especially in gain-sharing models.

There are some practical considerations for collaborating with Medicaid payers though, including Medicaid agencies themselves. These considerations have implications for Medicare's ability to harmonize cross-payer accountable care contracting models. First, because Medicaid eligibility is tied to income, patients' insurance coverage (or lack thereof) changes more frequently than for other patients. Additionally, Medicaid reimbursement rates are often lower than Medicare rates, and determined state by state, Traditional Medicaid providers like Federally Qualified Health Centers (FQHC) have alternative reimbursement structures, requiring additional model flexibility. For example, is an FQHC's "wrap payment" considered part of a patient's total cost of care or not? Finally, Medicaid covered patients can be harder to engage in clinical management for a variety of reasons, including barriers to preventive care access.

2. **What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?**

Given the wide variation between state Medicaid program designs, benefits and eligibility requirements, CMS will need to consider multiple accountable-care-based contracting models. Any model will need to consider state activities that leverage provisions within the Affordable Care Act in ways intended to drive more primary-care-based coordination for people with multiple chronic illnesses (e.g., health care homes) and state efforts to rebalance spending on long-term care services (i.e., Balancing Incentive Payment Program or BIPP), which account for almost 40 percent of all Medicaid expenditures. Models will also need to anticipate non-Title XIX monies used to support service delivery for people primarily insured by Medicaid. For example, counties may significantly influence how block grants and state-only dollars are used to procure a wide range of behavioral health services. Finally, CMS will need to consider state-specific health data privacy regulations, many of which are an additive to HIPAA.

3. **What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?**

From a Medicaid perspective, states could potentially play a role in model design, with a strong focus on aligning objectives and incentives, IT infrastructure, and data analytics. However, for these states to meaningfully contribute in these areas, additional funds would need to be provided to the states since many states do not have additional capacity to design and administer ACO-based programming. For example, some states have been able to support ACO activity, such as State Innovation Awards from CMMI, while other states like Minnesota and Iowa have ACO activity as a result of state legislation, much of which is unfunded, requiring the Medicaid program to redirect existing resources. Thus, CMS might consider supporting Medicaid collaboration on ACOs by extending enhanced federally matched funds for IT infrastructure. The business functionality needed by a state's Medicaid Management Information Systems (MMIS) to support ACO growth and effectiveness could be funded at existing enhanced match rates, with CMS effectively providing 90 percent of the dollars needed by states to develop the IT infrastructure needed to support proliferation of effective ACOs through a centralized data analytics "utility." Business functionality needed to support ACOs should be consistent with CMS' Medicaid Information Technology Architecture (MITA) vision for MMIS maturation—using the MMIS to support increasing Medicaid business functionality.

4. **What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?**

The ability of an ACO to obtain and work with Medicaid administrative data rests on both the state's MMIS and/or the quality and timeliness of encounters from Medicaid Managed Care

Organizations (MCOs) contracted to arrange clinical service delivery for Medicaid enrollees. Encounter data is notoriously poor quality; additionally, many state Medicaid agencies struggle to obtain Medicare data for use in understanding population risks and coordinating the care of people dually eligible for Medicaid and Medicare. Without significant regulatory changes enabling improved access to, and use of, Medicare data for state Medicaid programs, and improved encounter data quality, ACOs that attempt to serve Medicaid recipients and dually eligible patients will be forced to struggle with data that is old, incomplete and unreliable for purposes of timely care coordination and quality improvement.

5. **What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?**

Standardizing and aligning quality metrics, contracting simplification, data and claims definitions, data privacy common framework and performance models among payers clearly affords ACOs the opportunity to participate in ACOs by reducing the burden of these similar but not quite duplicate requirements.

Because Medicaid and Medicare pay for different components of care for people who are dually eligible, determining a coordinated or unified shared savings model is essential. Given state to state differences between Medicaid benefit sets for those who are dually eligible, ACO participation is more likely possible in a unified model, especially if there is simplification concerning the complexities of total cost of care for people in waiver programs accessing a wide variety of home and community-based services.

ACOs may have reservations about taking accountability for people in long-term care settings where most of the services accessed are not provided by integrated delivery systems, and therefore outside of any reasonable control in terms of price and quality. States are eager to explore mechanisms that manage long-term care costs, but until there is agreement about who keeps savings for specific service cost reductions between Medicaid and Medicare, including those who are dually eligible, it is likely to be unattractive to ACOs.

D. Other Approaches for Increasing Accountability

1. **A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?**

The "provider-led community" ACO model could benefit geographic regions with a limited supply of primary care practitioners and limited competition (e.g., sole community hospital towns, rural areas with critical access hospitals). Waivers could be extended to encourage clinical integration of all the willing providers and suppliers in the region and encourage the formation of a community-wide ACO. Critical design features should include broad participation of all segments including private employers and payers and involvement of public health and community resources including education. Organizers would benefit from CMS and Medicaid policy leadership in reducing barriers to data sharing, including the legal

expenses associated with interpreting state-specific regulation and crafting the many agreements needed between payers, providers and other community-based social services.

In addition to data privacy, CMS and Medicaid policy leadership will also need to address true interoperability in infrastructure components to support effective community-based care models. Influencing the infrastructure to be purposefully designed to transform practice-related data into useful, real-time information for all stakeholders collaborating to deliver better outcomes to individuals across systems of care would be a significant and worthwhile achievement. This type of innovation would enable true accountable care.

Critical success measures would be to control trends and achieve top-quartile utilization results. Critical quality measures could be expanded to address aspects of the communities' top health challenges (e.g., drug abuse, behavioral health, early pre-natal care).

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

Although we believe there would be interest in this topic, we suggest CMS pursue this layered approach through innovative grants.

E. Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

CMS can contribute to this endeavor by

- Ensuring success of the government ACO programs (i.e., Pioneer and Medicare Shared Savings Program)
- Continued collaboration with other agencies and states to remove barriers and increase operational efficiencies to fuel ACO membership growth opportunities involving dual-eligibles, Medicaid, and exchanges
- Collaborate with stakeholders to standardize quality measures and comparative data for scoring
- Provide up front funding for infrastructure that could be leveraged with other payer contracts
- Promote multi-payer contracts and standardized templates for contracting
- Provide additional incentives (e.g., shared saving percentage increase) to ACOs that are accountable for a substantial portion of a community's overall population

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

- Develop, update and maintain a single set of risk-adjusted quality measures and reporting methods applicable to all patient segments to be adopted by all payers
- CMS lead effort and collaborate with industry to eliminate the burden of multiple sets of quality measures

- Recommend an independent, respected organization be responsible for publishing and testing national quality measures and methods
- Leverage prior work of Integrated Healthcare Association in California and national organizations such as NCQA and NQF

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March 6, 2014

Marilyn Tavenner, M.H.A., R.N.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services

RE: Request for Information Regarding Accountable Care Organizations (ACOs) and the Medicare Shared Saving Program

The Pacific Business Group on Health (PBGH) appreciates the opportunity to comment on the RFI regarding the evolution of Accountable Care Organization (ACO) initiatives at CMS. For over twenty years, PBGH has helped purchasers nationwide to improve the quality of health care and to moderate health care cost increases. PBGH serves as a voice for purchasers, leveraging the strength of its 60 member companies which provide health care coverage to 10 million Americans. PBGH and its members have developed and operated myriad payment reform and delivery redesign initiatives and is pleased to contribute learnings from those efforts in these comments. We believe it is critical to maintain high standards and high expectations for payment reform and delivery redesign initiatives in the public and private sectors in order to drive needed and lasting change in the quality and efficiency of health care.

To truly transform the nation's health care delivery system into one that is person-centered, value-based, and coordinated, health information technology (HIT) must enable the interoperable exchange of high-value personal health data across settings of care and among patients and caregivers. As a cornerstone for delivery system and payment reforms, HIT will enable new models of care to share data and integrate it across sources (including non-EHR) and types of data (i.e., clinical, claims, and patient-generated data). Other Purchaser Principles that reflect our expectations and aspirations for these models of care include:

- Enhance quality and cost transparency
- Focus on outcomes measurement
- Support patient-centeredness in care delivery and measurement
- Promote pay for performance
- Improve affordability and access
- Support a competitive marketplace
- Alignment among public and private payers

Many PBGH members have experimented with accountable care models. For instance, CalPERS implemented an ACO-like pilot with Hill Physicians Medical Group, Dignity Health and Blue Shield of California that introduced a shared savings model for improving care coordination and quality for 42,000 HMO beneficiaries in the greater Sacramento area. Results showed a $20 million cost

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reduction over two years largely due to a 22% reduction in patient readmissions and shorter lengths of stay.[i, ii]

Similarly, Intel collaborated with Presbyterian Healthcare Services (PHS) to implement Connected Care, an ACO-like initiative that combines benefit design, plan design, and delivery optimization to give Intel employees and their dependents more personalized, evidence-based, coordinated, and efficient care. Connected Care went live on January 1, 2013.[iii] Connected Care uses a value-based compensation structure that includes both shared costs and pay-for-performance. This compensation system is based on a global per-member per-month target, with a shared-savings "corridor". Intel and PHS share risks and rewards if results exceed or fall short of a designated target. The program also includes a number of important patient-centered design elements such as 100% coverage of preventive care services, delivery system workflow redesign to improve patient experience, and patient access to secure digital communications and a comprehensive PHR.

PBGH also has experience taking a model used in the private sector and expanding it to a Medicare population. The Intensive Outpatient Care Program (IOCP) piloted by Boeing and other large employers is a primary care-led, high intensity care management model for high risk populations that features increased access and proactively managed care, waived copays for the initial intake visit, a per-member per-month case rate for non-traditional services on top of traditional fee-for-service payments, and shared savings.[iv] Over a two-year period, Boeing achieved improved health outcomes (28% reduction in hospital admissions, 16% increase in mental functioning on the SF-36), 20% reduction in costs, and increased patient access to care.[v, vi] Under a grant from the Innovation Center, PBGH has rolled out a similar model to 25 clinical sites in five western states, covering 23,000 Medicare patients, demonstrating commitment to public and private sector alignment.[vii]

These experiences have yielded useful lessons about how to implement and improve models of accountable care and along with our Purchaser Principles, are reflected in our response to the RFI. Please refer to the appendix for responses to specific questions. We appreciate the opportunity to provide input on a future round of the Pioneer ACO Model or another ACO program and look forward to collaborating with you in the future. If you would like to discuss any of these responses further, please do not hesitate to contact Stephanie Glier, Senior Policy Analyst, at sglier@pbgh.org.

Sincerely,

David Lansky, Ph.D.
President & Chief Executive Officer

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Appendix: Responses to the Request for Information

Section I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

Question A2: If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

We encourage CMS to reconsider this question. The success of the program does not depend on how many providers can participate; rather, the emphasis should be to ensure the program design yields better quality and more affordable care for consumers. The whole point of being *accountable* is being transparent about performance and making the necessary changes to make sure patients receive the best care at the lowest possible cost. Although some providers are not be able to meet the requirements for the Pioneer ACO Model, it lays out the expectations of what constitutes an "advanced" ACO should they want to participate in the program in the future. Many organizations already claim to be ACOs, but we do not want to pay more for the status quo.

Section II: Evolution of the ACO Model

Question A3: Are there services that should be carved out of ACO capitation? Why?

We support a move toward ACO capitation or other population-based payment models, and encourage CMS to use carve-outs sparingly and to maintain a simple payment structure as much as possible. We strongly encourage CMS to increase the financial stakes of performance and to put a greater share of provider payment at risk.

Question A8: What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

Large purchasers have set global budgets using recent years' expenditures with a target percentage reduction. These global budgets rely on local and regional reference expenditure growth trends, which may be a mechanism to help ramp ACOs interested in population-based payment arrangements that are not able to immediately meet a national target. In addition, we encourage CMS to rebaseline costs and expenditure benchmarks based on the best performers to establish minimum performance expectations and drive culture change around value-based payment.

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Question A10: What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

PBGH members implementing ACO initiatives have used benefit enhancements including lower share of premiums, lower or no co-pays for preventive services or for chronic condition management services delivered by ACO providers, and digital access to medical information and communication with providers. These benefit enhancements help direct patients to utilize care within the ACO network where care can be most effectively managed.

Question A13: Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

An important advantage of beneficiary-driven opt-in to an ACO is the buy-in on the part of the beneficiary to access care within the network of the ACO.

Question D1: A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

Quality measures for a community ACO should align with those measures required by the other programs affecting the population as well as with private sector initiatives in the community. Purchasers' priorities for improvement are better understood and more actionable if all head in the same direction and CMS's role as the largest purchaser provides extra leverage. We encourage CMS to use outcome measures and patient experience measures as much as possible.

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Question D2: In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

The Intensive Outpatient Care Program (IOCP) piloted by Boeing uses such a layered approach, with comprehensive primary care for the highest risk population within an ACO context. Although layering to segment the population is possible and in some cases useful to best care for patients with the greatest need, we encourage CMS to maintain simplicity in program and payment design as much as possible.

Question E1: How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

It is critical that CMS more actively catalyze multi-payer value-based purchasing arrangements, including ACOs. As demonstrated by the first performance year of the Pioneer ACO Model, misaligned financial incentives (e.g., predominantly fee-for-service payment arrangements) may dissuade providers from participating in ACO arrangements, or may lead to participants leaving ACO programs in future years.[viii] At the same time, CMS should establish and maintain a high bar for providers to participate in "advanced" ACO initiatives such as the Pioneer Model, and target the barriers preventing providers from delivering high-quality and efficient care. In many cases, private sector models like those described above require higher quality and greater efficiency than what is now included in CMS ACO models. Anecdotally, we have heard of providers pulling out or not engaging in private sector ACOs because it is easier to meet the requirements of Medicare ACOs.

Using a set of performance measures that is aligned with the private sector will reduce barriers to other payers participating, send a consistent signal to providers on what is important to purchasers and consumers, and require less effort collecting on the part of providers. The current ACO measures is a good "starter" set and CMS should rapidly implement better performance measures, with a focus on outcomes, patient-reported outcomes, patient experience of care, care coordination, appropriateness of care, and total resource use. For example, in the IOCP model PBGH uses measures of patient-reported outcomes (e.g., VR-12, PHQ-2) and patient engagement (e.g., Patient Activation Measure). Additionally the Connected Care program uses measures in five areas: (1) cost, (2) evidence-based medicine, (3) right time right setting, (4) member experience, and (5) return to function. These domains represent the highest priorities for the program and the measures within each domain are subject to modification every year.

While multi-payer initiatives can go a long ways to improving care delivery, it is important to address potential adverse consequences that can result from market dominance of ACO providers (e.g., increased prices for the private sector and cost-shifting) which contradicts the aim of reducing costs to the system. The Pioneer ACO Model is not strong enough to measure progress towards the goal

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of reducing system-wide costs. It is important for CMS to add requirements to the ACO program to build a more robust monitoring system for costs. In particular, CMS should:

1. Require all participating ACOs have a mechanism for assessing performance on private sector per capita costs by the second year of the program. An ACO itself does not necessarily have to have a mechanism in place, but could work with other stakeholders (e.g., using data from local purchasers or all-payer claims databases).
2. Gather data regarding current market shares, market entries and exits, and pricing trends for the ACOs. This information should be collected initially in the application process to establish a baseline, and then on an annual basis to monitor and report publicly on potentially adverse market impacts of ACOs.
3. Set expectations for resource stewardship and waste reduction, including public reporting of quality *and* cost metrics (e.g., cost to charge ratios, professional fee billing rates, prices for episodes for public and private payers, total costs for beneficiaries assigned to the ACO for public and private payers, etc.).
4. Hold ACOs in the Pioneer Program to a maximum threshold of price increase with their commercial market clients.
5. Move to requiring ACOs take part in all-payer claims databases (APCD). The APCD is a database comprised of medical, pharmacy, and dental claims, and information from the member eligibility, provider, and product files encompassing fully-insured, self-insured, Medicare, and Medicaid data.
6. Include community representatives, especially consumers and purchasers, on ACO governing boards

Question E2: How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

CMS should use performance measures that apply to a broad population including adults younger than 65 to promote alignment with other payers. Where possible, CMS can align with other payers by using performance measures already in use in the private sector. In addition to minimizing burden and enabling cross-cutting benchmarks and comparisons, the collection of claims data and performance information for the under-65 population will allow the assessment of any impacts of ACO-related market consolidation on care, prices, and spending.

Even when it is not possible for public and private sector ACO initiatives to require identical measures, use of similar measures or measures targeting shared concerns (e.g., reducing readmissions) strengthens the priority of these areas and makes it easier for providers to focus on these critical delivery system changes.

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Another option CMS could pursue is the required use of all-payer claims databases, which would allow various participating payers to obtain performance information needed even if program design varied slightly.

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[i] CalPERS Agenda Item 4. (2011, October 18). *Agenda Item 4 Memo to the Members of the Health Benefits Committee.* Retrieved February 21, 2012, from www.calpers.ca.gov: http://www.calpers.ca.gov/eip-docs/about/board-cal-agenda/agendas/hbc/201110/item-4.pdf.

[ii] Blue Shield of California Press Release. (2011, September 16). *HHS Secretary Kathleen Sebelius Reviews Key Pilot Program Tied to Health Care Reform Goals.* Retrieved June 3, 2013, from www.blueshieldca.com: https://www.blueshieldca.com/bsca/about-blue-shield/newsroom/sebelius-reviews-aco-pilot-programs.sp.

[iii] http://www.intel.com/content/dam/www/public/us/en/documents/white-papers/healthcare-presbyterian-healthcare-services-whitepaper.pdf

[iv] Additional information about the IOCP program can be found at http://www.pbgh.org/iocp.

[v] Milstein, A and Kothari P, Health Affairs, October 20, 2009. Accessed at http://healthaffairs.org/blog/2009/10/20/are-higher-value-care-models-replicable/

[vi] This model was also highlighted in Atul Gawande's "Hot Spotters" article in the New Yorker, and documented on the Agency for Healthcare Research and Quality (AHRQ) Health Care Innovations Exchange. http://www.innovations.ahrq.gov/content.aspx?id=2941. Additionally, Steve Jacobson, MD and Jennifer Wilson-Norton of The Everett Clinic presented on "Connecting Providers and Managing High Risk Beneficiaries" at the CMS ACO Accelerated Development Learning Session on September 16, 2011, https://acoregister.rti.org/docx/dsp_lnks.cfm?doc=Module 3B. Connecting Providers Managing High Risk.pdf.

[vii] http://www.pbgh.org/storage/documents/IOCP_Program_SumaryFeb_7_2014.pdf.

[viii] Toussaint J, Milstein A, Shortell S, Journal of American Medical Association, October 2, 2013. Accessed at http://www.pbgh.org/storage/documents/JAMA_Milstein_PioneerACO_10-2013.pdf.

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RESPONSE TO:

CENTER FOR MEDICARE AND MEDICAID INNOVATION
Request for Information
Evolution of ACO Initiatives at CMS

INTRODUCTION

Park Nicollet Pioneer ACO (P043) Structure:
Park Nicollet Health Services is an integrated care system that includes Park Nicollet Methodist Hospital and 25+ Park Nicollet Clinics encompassing 55 different multi-specialties. The system is based in St. Louis Park and has more than 8,100 employees, including more than 1,000 physicians on staff, providing care for residents in the Minneapolis and surrounding Western suburbs. Park Nicollet Health Services has a strong tradition of innovation in delivering care that simultaneously achieves the Triple Aim: improving the health of a population, improving experience; and reducing per capital health care costs. During the last decade we have been a leader in testing and implementing new models for health care delivery and financing for our patients and the community. Prior to joining the Pioneer ACO program, we participated with CMS in the Physician Group Practice (PGP) Demonstration.

As of January 2013, Park Nicollet merged with HealthPartners, the largest consumer governed, nonprofit health care organization in the country, creating an even more expansive footprint in the Minneapolis-St. Paul market. The combination of HealthPartners and Park Nicollet Health Services lays a strong foundation to leverage one another's assets in order to provide the best in triple aim care for the patients we serve. This integration has allowed us to optimize our strengths, building on the strong results of both organizations to create well-coordinated care across all levels of the care continuum for our patients. Our participation in the Pioneer ACO builds on our legacy of population health improvement. For example, Park Nicollet Health Services is an outstanding performer in Minnesota Community Measurement Optimal Diabetes (five individual measures), with 49 percent of patients meeting that aggressive standard in 2013. 90 percent of those same patients met the Hypertension measure under that Optimal Diabetes measure. The work we do to achieve these standards is one of the reasons why we as an organization support the goals CMS hopes to achieve with the Pioneer ACO program.

Market Dynamics: Minnesota's market is dominated by large, nonprofit integrated health care delivery systems, and non-profit health plans. There is a strong history of collaboration to improve care and work in new payment models that focus more on population health and total cost of care. Six integrated delivery systems account for more than 82 percent of the metropolitan area's inpatient discharges and three major insurers enroll the majority of the population in managed care and self-insured health plans. The most notable care providers are those that are also enrolled in the Pioneer program (Allina and Fairview), making a total of 3 Pioneer ACO's stemming from this low-cost Minnesota market.

Minnesota has one of the highest Medicare Advantage and Medicare Cost Plan penetrations in the nation (>45%). This impacts the composition of the regular, Medicare fee for service population that remains. There is strong medical group participation in health plan programs for Medicare beneficiaries in the region. The Pioneer ACO program is also a good fit for the region because of the population health emphasis, lower historical total cost of care, and high quality care for Medicare beneficiaries.

SECTION I: PART A, QUESTION 3 ONLY

Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

- **Risk Adjustment:** Lack of risk adjustment is a limiting factor in the Pioneer model. Because there is so much regional variation in the Medicare population's health status, more robust risk adjustment is needed to fairly compare aligned care and total costs. Using age, gender and eligibility status (consisting of Disability Status and End-stage Renal Disease) alone is not sufficient to capture changes in a population's illness burden. Adapting some of the risk-adjustment technologies already available to CMS (such as those for Medicare Advantage) would make for more valid comparisons. In addition, by using technologies that both CMS and providers have experience with, CMS could attract additional program participants.

- **Mortality Rate Adjustment:** Many Pioneer organizations have expressed ideas and options related to the mortality rate adjustment in the current Pioneer financial model. The mortality rate adjustment should be heavily modified from its current form, which has the potential to discredit the Pioneer financial model to key stakeholders. We understand that the model is using mortality to overcome weaknesses in the patient attribution protocol, and we understand the actuarial difficulty of dealing with end of life spending patterns. The overall "optics" of this adjustment would appear to benefit providers who have higher mortality rates. An example provided by Atul Gawande in 2012 illustrates the complexity and issues with the mortality adjustment. His speech on "Failure to Rescue" articulates his belief that rescuing people from near death is high quality care. An example of one of these 'rescues' is a very independent 88 year old patient who was admitted for a small bowel obstruction. His hospital course was complicated by aspiration pneumonia, respiratory failure, and kidney failure. He could have easily died. He was intubated, spent weeks in the Intensive Care Unit, weeks in an Long Term Acute Care unit, and is now in a Transitional Care Unit expecting to eventually and get back to independent living with a good quality of life. Because of this one "rescued" patient, an ACO could experience a $50,000 penalty according to the Pioneer Mortality Adjustment AND the patient's total cost of care for the year likely reached six figures. The current adjustment method assumes that the Pioneer ACOs' end of life spending patterns are the same as the average in the United States. The assumption may not be correct, given the well-documented intra-provider variations in such spending. We would recommend suspending this adjustment and allow each Pioneer to study its own end of life spending patterns. The Pioneers could then engage in more dialogue with CMS on this issue.

- **Quality Measures:** It is important that a program focused on a beneficiary's total cost of care be balanced with providing high quality care. The program's 33 quality measures must be sound enough to attract future participants and garner their support, as future ACO participants will need the support of their clinical teams to adhere to these measures as much as realistically possible. It is understood that there is ongoing evolvement associated with some of the measures, but there is more work to be done to assure that the measures are interpreted clearly, and the specifications associated with measurement numerators, denominators and exclusions reflect best practice and actual performance. There are some outstanding areas for which clinical concern is currently warranted, for example:

  - **(ACO #30) Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic**
    The combination of anticoagulants with antithrombotics is dangerous and rarely indicated, and therefore is problematic for this measure. There must be either an exclusion allowed for patients on anticoagulants or allowing anticoagulants to count in the numerator. There must also be exclusions for contra-indications to

antithrombotics (e.g. allergies, history of GI bleeding, history of intracranial bleeding). The diabetes aspirin/antiplatelet measure is much better defined due the fact that patients with a contraindication (allergy/intolerance to aspirin/antiplatelet, on anticoagulant, history of GI bleed, etc) are included in the numerator. If organizations are performing at 95% without exclusions there is potential that harmful care may be taking place.

- **(ACO #21) Screening for High Blood Pressure**
  The pre-hypertensive cut offs are based on JNC7 expert opinion guidelines - evidence for rescreening is STRONG. The follow-up rescreening intervals in the specifications are arbitrary and of WEAK evidence. In the US, there are a fairly small percentage of people with HTN who are undiagnosed.

- **(ACO #13) Screening for Falls Risk**
  There is no clear evidence-based benefit for community-based elderly to screen for falls risk. "The USPSTF does not recommend automatically performing an in-depth multifactorial risk assessment in conjunction with comprehensive management of identified risks to prevent falls in community-dwelling adults aged 65 years or older because the likelihood of benefit is small."

Quality Benchmarks: While benchmarks based on empirical evidence is a move in the right direction compared to the initial flat percentage methodology, 100% benchmarks for the influenza immunization, pneumococcal vaccination, adult weight screening and follow up, and colorectal cancer screening measures (and 99% for breast cancer screening) do not reflect a realistic benchmark. This is very important, as organizations will commit extensive resources to improvement, and will need the support from the clinical teams. A better solution is to account for results that are based on post- quality audit results as well as to incorporate weighting of the results for groups that have as low as 20 cases. This will assure that the program is able to provide full set of realistic benchmarks to which ACO organizations are expected to perform.

Quality Submission Process: The methodology used to submit quality performance measures has been changed from PY2 to PY3. The PY2 approach, - a web based application with GPRO, worked well and accomplished the reporting with a reasonable administrative effort. The new - method of using the QMAT tool which requires the use of QRDA 1 to submit data, truly requires the engagement of the organization's electronic medical record (EMR) in order to hard code the capabilities to generate the files within our EMR in order to submit data. Without this partner, the ACOs will experience an even heavier burden to submit quality measure data, forcing intensive and costly manual entry data submissions. We fundamentally agree with having a common file type for data exchange, however this must be supported by EMR vendors to succeed and may prohibit some from participating in this type of program.

SECTION I: PART B, QUESTIONS 1-4

Population-Based Payment

1. **Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?**

No, being able to choose different Part A and Part B reduction percentages would not be of significant importance to us because Park Nicollet is an integrated system with significant Part A and Part B services. Though it would allow ACOs to have more flexibility implementing PBPs, having the option to choose different FFS reduction amounts would not drive our decision to participate in the PBP model.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

No, DME is a small portion of overall claims. Including these suppliers in the list of providers receiving reduced FFS payments is not important to us.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

Yes, Pioneers should be able to participate in PBP regardless of savings levels. If the ACO is willing to establish the necessary financial reserves and if the ACO is willing to set up the proper accounting for PBP payments, the ACO should be able to participate in the PBP system. This would allow the ACO to learn and get experience with the PBP system. And, due to a different cash flow model, this may also allow ACOs to more quickly implement change to improve care for the patients they serve.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

At this time no, but it is difficult to comment without having experienced the current PBP system.

SECTION II: PART A, QUESTIONS 9, 11, 13 ONLY

Evolution of the ACO Model: Transition to greater insurance risk

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

(Answer is also mentioned previously in Section I, Part A, Question 3)

The Pioneer ACO model uses 4 population characteristics to essentially depict the risk associated with the ACOs population relative to the reference population: Age, Sex, Eligibility (consists of Disability Status and End-stage Renal Disease), and the Mortality Adjustment. The simplicity of this methodology over-weights these factors. For example, under this model, ACOs who are more aggressive at preventing end stage renal disease may perform worse financially. High functioning ACOs who are better at life-saving treatments may have lower mortality rates yet perform worse financially because of mortality adjustment.

It is recommended that the Pioneer ACO risk adjustment methodology:

- Eliminate or at least make optional the Mortality Adjustment as a risk adjuster in the Pioneer ACO model.
- Use HCC risk adjustment. HCC risk adjustment has been well-tested and validated and would offer a more valid comparison of risk than the current 5 factors used in Pioneer. HCCs are used in Medicare Advantage, and harmonizing risk adjustment methodologies between MA will facilitate payment neutrality between Medicare Advantage and ACOs. CMS could adapt some of these risk adjustment technologies that are available to CMS for more valid comparisons.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

Any entity that takes on insurance risk will be faced with potential integrity issues of adverse selection and underuse of necessary care. Well-tested and validated risk adjustment models are required to minimize adverse selection. The utilization of HCC risk adjustment which has been extensively studied and used in Medicare and will facilitate better comparison of Pioneer and Medicare Advantage outcomes. In addition, a strong foothold must be sought to assure accountability for quality and patient experience outcomes so that full risk ACOs are not perversely incented to underuse necessary care. Therefore, it is imperative that CMS continue to push for quality and experience outcomes that are supported by data and are consistent with achievable results.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

Allowing beneficiaries to elect alignment with a Pioneer ACO would allow Pioneer ACOs to engage with beneficiaries who choose us, but may be infrequent users or new Medicare enrollees that currently are not attributed to the ACO in the normal process.

SECTION II: PART B, QUESTIONS 1-3

Evolution of the ACO Model: Integrating accountability for Medicare Part D Expenditures

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

Many ACOs have little experience with creating and managing Part D plans. CMS would need to educate ACOs and guide them through the steps if they wanted a lot of participation in this program. Perhaps consider naming champion ACOs that already have maneuvered through the complexities of understanding Part D claims, data and risk through Medicare Advantage plans to present some of their findings and experience about the method and process they used. Any initial movement in these programs would need to be **voluntary** for those organizations that have interest and capacity to manage this change. In addition, the program would need to be able to provide timely, complete, and accurate Part D claims and reports that would enable ACOs to manage prescription drug utilization. Another option would be to work with ACOs that are part of integrated financing and health delivery organizations (health plans and ACOs) to look at new potential models to incorporate Part D.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

In order to accept full Part D risk, ACOs would need to be assured that they would have timely access to all PBM data and expense information for all of the at risk members.

Creating a separate Part D expenditure target and relying on the current bidding process makes the ACO model even more complex. It is unlikely that many ACOs have the necessary experience or knowledge to create and implement a plan like this effectively and quickly. CMS might need to start ACOs with no or limited risk so that Part D management experience could be gained before accepting full risk.

Unifying the expenditure target for Part A, B and D seems more straightforward because there is just a single target that is being set. Also, this aligns with the goal of using total cost of care as the measure of success. The blended expenditure target means that an ACO would need to deliver lower total costs overall---both medical and prescription drug. If there were separate expenditure targets, the ACO could be successful in one and not the other---for instance an ACO could do well on prescription drugs but not on medical services.

3. **Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?**

No, ACOs do not currently have enough data to accept full Part D risk because we do not know what we do not have. We get some Part D claims, but we have no way to know how many patients are in employer sponsored retiree plans or in other prescription plans that are not processed by CMS. For those patients that do not have prescription data, we do not know if they truly had no prescriptions filled or if they are not enrolled in a CMS administered Part D plan. ACOs would need to be educated on these issues and we would need to learn more about intricacies the Part D payment process.

SECTION II: PART C, QUESTIONS 4 & 5 Only

Integrating accountability for Medicaid Care Outcomes

4. **What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?**

We are using the Medicare FFS complete claims data to risk stratify our patients and to identify those patients which could most benefit from a high level, more orchestrated level of care coordination. By using this data to create provider specific panel reports, we are trying to improve cost, quality and patient satisfaction. Using this information in a risk stratified method, allows care teams to conference together to review patients at risk, which triggers appropriately aligned follow up. This follow up is documented in the medical record, viewable by all care team members throughout our integrated system. Though we are still learning and our process is still evolving, we believe we are making strides in the use of the claims data to better patient care.

We have very limited ability or experience integrating other community care or non-traditional care providers into our EMR.

5. **What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?**

We do not foresee full capitation risk for ACOs in either Medicaid or Medicare in our market. For our own organization, our health plan participates in Medicare Cost, Advantage and in Medicaid with the State of Minnesota. Our combination with HealthPartners allows us to work in many financial models under these products, and continue to work on consistent population health improvement through aligned quality metrics across these types of plans. Other than full capitation, a separate, but coordinated shared savings approach would be our recommendation- using total cost of care as the measure of success. HealthPartners pioneered a total cost of care methodology and measure that was endorsed by the National Quality Forum and this measure is now used across the country in many states to measure total cost of care. On the issue of combining Medicare and Medicaid populations, they differ significantly and would therefore require the establishment of separate targets and models as well as a variation in the work we do to support the total cost of care work.

Center for Medicare and Medicaid Innovation
Request for Information: Evolution of ACO Initiatives at CMS

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.
ACTION: Request for Information (RFI)

SUMMARY

The Centers for Medicare & Medicaid Services (CMS) are seeking input on the following areas related to the evolution of Accountable Care Organization (ACO) initiatives.

1. A second round of applications for the current Pioneer ACO Model

2. New ACO models that encourage greater care integration and financial accountability

DATES: *Comment Date:* To be assured consideration, comments must be received by March 1, 2014.
ADDRESSES: Comments should be submitted electronically through the CMS Innovation Center's web page at: http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/
FOR FURTHER INFORMATION CONTACT: PioneerACO@cms.hhs.gov with "RFI" in the subject line.

BACKGROUND

Section 1115A of the Social Security Act, as enacted by section 3021 of the Affordable Care Act, authorizes the Center for Medicare and Medicaid Innovation (hereafter, the Innovation Center) to test innovative models of payment and service delivery that have the potential to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid and CHIP beneficiaries.
The Innovation Center's Pioneer ACO Model was designed to complement the Shared Savings Program, established under Section 3022, by offering participating ACOs a distinct set of payment arrangements and different methodologies for performing beneficiary alignment and expenditure calculations. The Pioneer ACO Model was also designed as a testing ground, where certain design elements could be developed and tested before being considered for incorporation into either the Shared Savings Program or another CMS program.
CMS is issuing this Request for Information (RFI) to obtain input on policy considerations for the next generation of CMS ACO initiatives. Topics of particular interest include (1) approaches for increasing participation in the current Pioneer ACO Model through a second round of applications, and/or (2) suggestions for new ACO models that encourage greater care integration and financial accountability.

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes based contracting. The Model is now entering its third performance year with 23 organizations. In addition to increasingly aggressive risk arrangements, CMS offers eligible Pioneer ACOs the opportunity to transition from fee-for-service payments to monthly population-based payments to give these organizations more revenue flexibility in determining how to best motivate providers to improve quality of care and reduce costs for their patient populations. As more and more health care organizations begin to hone their skills in care coordination and engage in outcomes-based contracting, CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

B. **Population-Based Payments:** CMS allows Pioneer ACOs to transition to population -based payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a 40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

Partners HealthCare does not have a particular position on the above question. However, given the findings by Reschovsky et al. in Health Affairs 2012 demonstrating that home health and durable medical equipment were major drivers of total geographic service use variation because of their variation across sites (as an example), we would encourage CMMI to consider retroactive reconciliation for fraud and abuse recovery. We recognize recovery efforts would occur many times beyond the performance period. Despite this timing challenge, efforts made to include fraud recovery as part of potential shared savings may encourage providers to increase their already significant efforts in identifying and combating Medicare fraud and abuse.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

Total Medical Expenditure trend will decrease over time through more coordinated, accountable care. This requires providers to invest in innovative clinical programs that may or may not provide a return on investment within the time period of the contract, but are critical for long term success in population health management.

As organizations like ours invest heavily in information technology and human resources to coordinate care, we inevitably do so at a level greater than expected short-term savings. Systems like ours would benefit if some dollars were not at risk over the short-term. This cash flow could be channeled through the PBP with reconciliation delayed 5-10 years. Health systems could then take a longer-term view and invest more aggressively in transformative capital investments on which they may not see a return for 5-10 years.

Partners HealthCare would like a PBP that is not reconciled to actual claims. The PBP payment would be an expense against the benchmark. However, by not reconciling it to actual billed claims, it would allow an ACO to provide more non-billable services while not greatly affecting their current reimbursement level.

Section II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:

• Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;

• Give providers more tools and resources to improve care outcomes and efficiency; and

• Continue to preserve beneficiary freedom of choice in FFS Medicare.

CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

A. **Transition to greater insurance risk** –ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues.

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

Partners HealthCare would consider a modified version of capitation. A sub-capitation could be an alternative to this approach where a system would receive capitation payments based on the services they provide and be responsible for the claims paid outside of their system but not be responsible for the actual FFS claims payment.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

Providers should ideally be at risk for all costs incurred by beneficiaries – e.g. facility, physician and drug costs. By limiting services it limits the opportunities for a provider to implement effective programs. This is predicated on the availability of claims data in order to manage these expenditures. Without the data a provider cannot implement effective programs and should not be expected to be at risk. This is clearly most challenging for Part D claims.

3. Are there services that should be carved out of ACO capitation? Why?

Any service where incomplete or lack of claims data should be considered for potential carve-out for ACO capitation. Without the availability of data, providers will be challenged to fully capture the opportunity to control those expenses.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would *not* be appropriate for ACOs assuming full insurance risk?

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

See question 4

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

As stated in the previous questions moving to full capitation would be a major undertaking for a provider system. One of the biggest obstacles would be claims payments to non system providers.

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

Partners HealthCare is not in support of continuing the current national trend benchmark approach for the long term on the Pioneer ACO program. Partners HealthCare would support a benchmark that encourages the long term predictability of medical trend or a Normative Rate. Partners HealthCare is also concerned about baselines that reset frequently, given the investments that organizations must undertake and the continuation of these investments to achieve trend reductions a resetting baseline makes it difficult to achieve the necessary savings to offset these investments.

Additionally, our provider system is in a state where there is a cost-growth benchmark as part of comprehensive health care reform. It would be ideal to have national and state payment systems in alignment where possible.

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

Classic risk adjustment with claims coding have the downside of being subject to billing manipulation. The decedent adjustment also has several issues. First, the novel nature of using this sort of risk adjustment and secondly, the optics of adjusting payment rates based on death rates should be major considerations.

10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

We do not have specific suggestions, but broadly, CMS should consider enhancements that may increase patient engagement and reduce leakage and will ultimately improve a provider's ability to offer improved care coordination.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

Questions 9-13 address a move toward a "Medicare Advantage type model" Partners HealthCare would be interested in a model but there are some large concerns as raised with this question:

- *Member attribution could no longer be the beneficiary alignment, members would have to select a PCP and a form of referral management or member incentive would have to be in place to support integrated care. The selection of a PCP is necessary so the member is aware they are opting in to this model.*

- *Risk adjustment would have to be incorporated. Demographic adjustment would be a preferred addition.*
- *Underlying insurance risk would need to be addressed. State Division of Insurance oversight must have guidelines that adhere to the same standards as insurance companies but also provide ease and support that meeting these guidelines is not a barrier to participation.*
- *The benchmark methodology would have to be rationalized to not be a trend improvement but similar to Medicare Advantage where an absolute benchmark would need to be achieved. Pricing would also need to be standardized for major non geographic pricing adjustments like IME and DSH*

B. **Integrating accountability for Medicare Part D Expenditures**– An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

Partners HealthCare is in support of integrating Part D expenditures but does not have enough background to understand all the nuances of working with PDPs. Pharmacy expenses are part of overall healthcare expenses and are under the complete continuum of care Partners HealthCare is managing for all of our members. If Part D expenditures were to be integrated, providers must have access to the claims data for their beneficiaries regardless of whether the member has a PDP or not.

C. **Integrating accountability for Medicaid Care Outcomes** – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

An ACO accountable for Medicaid outcomes would potentially fill existing gaps in care delivery by moving clinical care management activities to the point of care and aligning incentives more effectively at the provider level. To be effective for Medicaid members, an ACO would need to coordinate with behavioral health, social services, and community organizations. Commercial or Medicare patients might benefit from better coordination among primary care doctors and specialists, many of whom do not

see Medicaid patients. There might be challenges to aligning key ACO components, such as quality metrics, which may not be relevant for all patient populations.

The potential for better coordinated care offered by Medicaid ACOs may be particularly promising for beneficiaries who will be covered through the Medicaid expansion. This population will include primarily low-income, childless adults, many of whom have gone without health care for extended periods of time. One critical challenge with this population is the difficulty attributing and assigning new patients to an ACO, due to the lack of claims history. Since this population may have a very different risk profile from current Medicaid enrollees, it is unclear how to adjust shared savings methodologies appropriately, without putting the ACO at risk for unintended losses.

Coordination between Medicaid and Medicare ACOs is particularly important for dual eligible. State enrollment policies in dual eligible programs should not be allowed to trump participation in a Medicare ACO, as we understand the case to be in New York.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

Medicaid ACOs will require significant infrastructure which may be too resource intensive for states already involved in the integrated care initiatives for Medicare-Medicaid enrollees in addition to state payment reform initiatives. Ultimately, success will depend on the skills and knowledge of the state Medicaid staff and the level of support and leadership provided by CMS. It would be very valuable for CMS to provide states with financial support for developing a Medicaid ACO initiative. A competitive process which awarded even modest amounts of CMS funds to states which are able to elicit significant financial and other commitments from foundations, insurers and delivery systems, and other organizations with a strong commitment to improving systems of care would be a useful approach to consider.
CMS and state Medicaid agencies must determine the range of services for which these organizations should be held accountable. Ideally, the ACO will be responsible for coordinating care across the complete range of health services used by a particular patient, and potentially services that extend beyond health care

States will also need to consider how ACOs align with existing state programs, such as Primary Care Payment Reform (PCPRI), Patient Centered Medical Home Initiative (PCMHI), the Duals demonstration and other alternative payment models, to avoid duplication of payments or services. States should also be clear about the services that existing programs already provide and the delivery gaps that ACOs will be expected to fill.

In addition, states will need to select appropriate quality measures, measurement strategies, and value-based purchasing techniques. Medicaid agencies should align metrics with existing efforts to ease data collection and quality reporting requirements for providers, plans, and the state. Measures should also align with the goals of the ACO, which may focus on a particular health need or complex population

versus ensuring their broader Medicaid population benefits from their model. It should be noted that ACOs that target a small subset of super-utilizers among their attributed patient population may not have sufficient patient numbers to reliably measure changes in quality

ACOs are a vehicle for pushing the locus of responsibility for patient care and the appropriate financial incentives down to the practice level. For this model to be effective, the relationship between ACO providers and health plans must evolve. The latter's roles and responsibilities will need to be reconfigured in ways that better support provider-level innovation and accountability. Health plans have traditionally supported providers by overseeing utilization review, delivering disease and care management programs, and managing quality measurement and system-wide performance improvement efforts. With ACOs increasingly assuming the responsibility of care management, health plans must decide how best to support providers in these efforts. State agencies can support this delineation of roles.

It may be useful to ask organizations that include both delivery system components and insurer components to describe innovations that they have successfully implemented in which role delineation is clear and in which evolving the plan and provider roles has produced better outcomes both clinically and financially.

State Medicaid programs often have close relationships with community health centers. It would be useful for CMS to encourage states to identify community health centers which are already organized as patient-centered medical homes and have begun to function (more or less formally) as though they are operating in ACO-like frameworks.

On a related note, because Medicaid is frequently not a durable benefit over a potential beneficiary's life, the ACO will be constantly at risk for a changing population. States should consider rule modifications that may temper the annual churn in Medicaid enrollment, and ultimately support care continuity under ACOs.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

CMS, states and ACOs will need to develop the capacity for collecting and analyzing Medicare and Medicaid data, as well as to store and manage that data.

At a minimum, ACOs will need timely access to combined Medicare and Medicaid claims based data (particularly for emergency room visits), the skills to effectively analyze the data, and the ability to translate that information into care management activities. Timely data will be needed to feed electronic disease registries, clinical decision support, predictive modeling, and other analytic software. A health information exchange across delivery system partners will be essential for efficient care coordination. There is limited ability of current electronic medical records systems to integrate external data such as claims data. We are currently aggregating external data into an enterprise data warehouse and are spending significant time defining methods to bring the insights from this data into clinical settings.

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

The cost drivers of Medicaid patients vary greatly from those of commercial and Medicare populations, due to mental health, substance abuse, and socioeconomic instability. For Medicaid beneficiaries, ACOs must knit together medical and social service financing and delivery at the community level and deploy those resources more effectively to improve outcomes.

Setting rates to predict service utilization for a complex population with a wide range of health needs is a complex process, thus CMS and the states should collaborate to:

- *Build risk adjustment models to fully capture health status and service use, and to target payment appropriately*
- *Apportion risk and savings between the state, CMS, and ACOs*

The preferred financial arrangement would be a separate but coordinated shared savings arrangement that reflects combined Medicare and Medicaid expenditures. Recognition must be given to the technical assistance that may be required for current safety net providers, e.g. Federally Qualified Health Centers, to be able to deliver services in an alternative payment model.

As observed in the Financial Alignment Demonstration (duals), risk adjustment and timing of rate development as it relates to implementation deadlines are crucial factors.

D. **Other Approaches for Increasing Accountability** – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for *all* Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

E. **Multi-Payer ACOs** – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

Partners HealthCare applauds CMS' commitment to measuring quality utilizing electronic health record data from providers. CMS should advocate that other payers adopt this approach. CMS can play a central role in coordinating disparate quality reporting requirements from various payers. Partners HealthCare recognizes that there will likely be a need for payers to require some payer-specific quality reporting. However, CMS can and should lead a process with relevant stakeholders to increase quality measurement based on electronic medical record data (as opposed to claims data) and to harmonize EHR measures across payers.

Center for Medicare and Medicaid Innovation

Request for Information: Evolution of ACO Initiatives at CMS

DATES: *Comment Date:* To be assured consideration, comments must be received by March 1, 2014.

ADDRESSES: Comments should be submitted electronically through the CMS Innovation Center's web page at:

http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/

FOR FURTHER INFORMATION CONTACT: PioneerACO@cms.hhs.gov with "RFI" in the subject line.

Section I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters – No comments.

Section II: Evolution of the ACO Model

A. Transition to greater insurance risk

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?
    a. The impact of allowing a beneficiary to elect alignment to the Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology would vary according to the attribution model selected by the ACO. The advantages and disadvantages of attribution methodologies have been much discussed as Pioneer ACO and other accountable care organizations are implemented. Adding the option of patient self-attribution would create additional complexity, though the overall impact of such a change in policy would depend on the actual numbers of patients who chose to self-attribute. For ACOs using a prospective attribution model, the addition of new beneficiaries after the start of the performance period could negatively affect strategies or initiatives developed by the ACO's providers to target their known panel composition. If the ACO has chosen a retrospective attribution period, the impact would depend on the criteria being used. If the beneficiary joined early in the performance period and met the standard attribution criteria, the impact would likely be minimal. However, if beneficiaries were not required to also meet certain utilization requirements, the impact might be greater. In either circumstance, we see the need for a balance between freedom of choice for beneficiaries and the need for ACOs to manage their care quality and costs.

B. **Integrating accountability for Medicare Part D Expenditures**

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?
    a. Accepting full risk for Part D expenditures requires timely and sufficient access to Part D data as well as sufficient support for data management and processing. In order to effectively utilize Part D data to improve care quality and outcomes, ACOs must have access to reasonably complete data with minimal lag time. The currently monthly delivery may be sufficient for clinical use, however the lag time between the event and the delivery of the Part D data must fall within clinically relevant thresholds to fully support ACO activities. The ACO must then have sufficient staff resources and expertise to analyze the data, integrate the information gained with the Electronic Health Record (EHR), and ensure that relevant quality improvement programs have access to the information. Each of these may present barriers to use of such data; the technical process of integrating claims data with EHR data for quality improvement use is in itself a significant challenge.
    b. We agree that ensuring ACOs have access to Part D data and working to improve the timeframe for data delivery would support the overall goals of the organization; prescription drug utilization is well documented to affect ambulatory care-sensitive hospitalizations and other key health outcomes. However, we note that ACOs may not yet have routine, reliable access to Part D plan drug formularies. Access to formularies within the EHR would enable an ACO to develop best practices guidelines and educate providers on opportunities to reduce costs and improve care, as well as facilitating each

provider's efforts to adhere to guidelines. Checking drug formularies within the EHR is currently a menu measure for eligible professionals working towards Meaningful Use attestation. We therefore suggest CMS explore opportunities to ensure that Part D plans provide updated, accessible formularies to ACO participants.

C. Integrating accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?
    a. We support the proposal to encourage ACOs to assume responsibility for Medicaid outcomes, but request clarification on the specific details of such an expansion of ACO responsibility. By using the infrastructure that Medicare ACOs have developed, CMS could expand access to the coordinated care delivered by ACOs to Medicaid beneficiaries in an efficient manner: now that ACOs are up and running, the additional effort required to expand services to additional populations will be much less than that required to stand up new ACO systems. However, an expanded ACO model would require support to develop expertise in newly targeted populations. We request clarification on the following aspects of a Medicaid ACO model:
        1. Model Structure: Medicaid populations may have significantly different needs and present a different case mix, and ACOs may therefore need to develop new strategies, programs, and relationships to manage Medicaid outcomes. One option may be to use a staged model, mirroring the existing Shared Savings Models, which would allow ACOs to shift from a one-sided to two-sided model after an initial period, thereby allowing time for the development of new expertise and resources.
        2. Administrative structure: We also request clarification on the intended reimbursement and attribution processes, as Medicaid is a state-by-state program and includes both Fee-For-Service and Managed Care. Would ACOs be required to work with their State Medicaid office to determine the specifics for their state, or would CMS manage the reimbursement and attribution processes centrally? We are particularly interested in the planned administrative structure, as New York State Medicaid includes at least 15 managed care plans alongside Fee-For-Service, creating a potentially complicated landscape. If Medicare ACOs expand to include accountability for Medicaid outcomes, consistency in the model structure and administration will be important to minimize burden and maximize the ACO's ability to incorporate additional populations.
        3. Relationship to existing programs: Would this proposal replace or build upon the Financial Alignment Initiatives currently underway in certain states? An integrated care model incorporating accountability for Medicaid outcomes would benefit from the lessons and experiences of the Financial Alignment Initiatives models currently being tested, however these demonstrations run through 2017. Many State Medicaid programs and Medicaid managed care organizations already have contracts with providers for related programs; we would appreciate insight into CMS's proposed approach to developing a coordinated Medicaid ACO program. Similarly, several states are currently exploring or implementing Medicaid ACO-type models, including New York State's Health Home model; would this proposed new model aim to incorporate or replace the existing programs?
        4. Contract structure: We are unclear as to whether the goal is to create a combination Medicaid + Medicare ACO model in which the same ACO has accepted responsibility for all Medicaid and Medicare outcome, versus a model in which an ACO could choose Medicare only, Medicaid only, or both.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?
    a. We support the suggestion to prioritize dual-eligible beneficiaries treated by the ACO historically. Initially, prioritizing beneficiaries already treated by the ACO seems likely to ensure that the ACO is already familiar with the specific needs of the Medicaid beneficiaries being integrated into the ACO. Accepting accountability for all Medicaid beneficiaries as well as CHIP beneficiaries would represent a significant expansion of the ACO's overall risk and responsibility, and we suggest such an expansion may benefit from an initial 'pilot' period during which reimbursement, attribution, data access, and other

administrative components can be tested and refined. Experiences from the existing Financial Alignment Initiative Demonstrations may be useful in facilitating the data access and other specific needs related to dual-eligible beneficiaries. The proposal to create accountability for all beneficiaries residing in a specified geographic area appears better suited to certain areas in which all or nearly all of the providers in a given region are members of the same ACO; we are not aware of a potential benefit to such an arrangement in geographic areas in which there are multiple ACOs and/or many non-ACO providers.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?
    a. In considering the role of States in providing support, incentives, and other resources for ACO initiatives, we note that certain other organizations may be able to provide significant support to ACOs in coordination with both CMS and States. These include the Regional Extension Centers established to support the Meaningful Use EHR Incentive Program, which have developed expertise in providing support to practices and providers seeking to utilize Health Information Technology (HIT) to improve care; Regional Health Information Organizations, which can support ACO data needs through health information exchange; and, potentially, organizations under the new Quality Improvement-specific QIO model recently proposed by CMS. While there will be substantial state-by-state variation, the integration of these existing resources with any additional resources, including multi-payer databases, can provide support to new ACO initiatives. These organizations may additionally be able to support efforts to integrate and streamline reporting requirements to ease the burden on individual practices and ensure high quality data and reporting. However, given the existence of Medicaid ACO and ACO-type models already underway in a number of states, the resources available to support new models may depend on the degree of integration with existing programs.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?
    a. Integrating and using data from additional sources is a challenge for providers. Community-based ACOs that include providers on multiple different EHRs face additional difficulties in sharing data across vendors. Integrating claims data received from external sources with EHR data for use in driving care improvement and performance reporting requires extensive technological capacity and knowledge, and may not be possible for most ACOs at this point in time. Promoting drivers of interoperability between vendors and across data sources will be of particular importance to ACOs as they seek to utilize claims and other data for quality improvement. Integrating information on care received in the community or from other non-traditional care providers is similarly difficult, particularly if the care provider in question does not use an EHR or, just as vital, Health Information Exchange (HIE). The process of patient matching remains a challenge even if data from multiple sources is available; without consistently effective and reliable patient matching methods, ACOs will not be able to meaningfully use FFS or other data in conjunction with EHR data. We suggest that CMS could play a role in promoting HIT overall, including EHR, and data analytics vendor capabilities regarding integrating multiple sources of data in addition to driving provider interest. Through the EHR Certification requirements and other programs, CMS has the opportunity to drive vendors to focus on interoperability over the longer term. However, as the EHR market matures, many providers will continue to use existing products and may not update to the latest versions within the timeframe needed to support the proposed new models. We therefore see a role for CMS in the shorter term in developing and promoting best practices for gathering and exchanging data from non-interoperable EHRs. Finally, in addition to the baseline technological capabilities required, we see a role for Regional Extension Centers or other quality-focused organizations to support ACOs in developing efficient, useful data management processes to support care improvement and quality reporting.

D. **Other Approaches for Increasing Accountability**

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?
    a. In the experience of the New York City Regional Extension Center, providers are frequently interested in pursuing multiple quality improvement, quality reporting, service delivery, and payment reform initiatives. We therefore suggest that CMS should consider formalizing one or more models that explicitly combine various service delivery and payment reform initiatives. We would suggest that considering the financial, reporting, and other interactions among federal programs, e.g. Meaningful Use, ACO, PQRS, State programs, e.g. Medicaid advanced primary care models, and non-governmental programs, e.g. Patient-Centered Medical Home, would be helpful for both CMS and for all stakeholders as these programs achieve wider adoption among providers.
    b. Key features for such a "layered" ACO would include alignment of program reporting requirements. One existing mechanism for such alignment is the inclusion of attainment of Meaningful Use as a measure for an ACO model. Broadly speaking, assessing whether reporting on a specified set of measures could be used for multiple programs as well as whether participation in one program could 'count' towards another would inform the most critical aspects of such programs. An existing example of such an effort is the 2013 PQRS-Medicare EHR Incentive Program Pilot, which would allow eligible professionals to meet the clinical quality measure requirement for the Medicare EHR Incentive Program and simultaneously meet the requirements for the PQRS program. Such formal integration further promotes provider engagement and clarifies the integral relationships among the various programs.

E. **Multi-Payer ACOs**

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?
    a. We strongly support overall efforts to focus quality reporting on top priorities, including focusing on areas of highest healthcare burden and addressing top causes of morbidity and mortality as well as of cost, while working to minimize duplication and excess burden. We see three inter-related areas in which CMS and other payers could focus to move these efforts forward.
    -Work with industry partners, e.g. America's Health Insurance Plans, as well as State Medicaid to coordinate across plans on specific quality measures, thereby streamlining reporting requirements at the highest level.
    -Work with vendors to encourage development of HIT tools for easier reporting, e.g. by incorporating key measures into care coordination documents and focusing on interoperability among EHRs, to facilitate the actual calculation and reporting process both within ACO models and across Federal, State, and payer programs.
    -Working internally to expand the use of unified reporting systems like the Group Practice Reporting Option, to minimize duplication across various programs.

PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

February 28, 2014

Centers for Medicare and Medicaid Services
Center for Medicare and Medicaid Innovation (CMMI)
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submit to: PioneerACO@cms.hhs.gov

Dear CMMI:

Re: Request for Information: Evolution of ACO Initiatives at CMS

We appreciate the opportunity to comment on CMS' Request for Information: Evolution of ACO Initiatives at CMS. These comments are submitted on behalf of the Pharmaceutical Care Management Association (PCMA), the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, and Medicare. PCMA members are committed to providing low-cost, quality, safe and effective pharmacy benefit programs to our clients and their employees and policyholders.

We are particularly interested in CMS' efforts directed toward transitioning ACOs to full insurance risk and holding them accountable for total Medicare expenditures (including Parts A, B, and D). Of the questions asked in the RFI, we focus primarily on the laws and regulations that affect the ability of ACOs to establish business relationships with Part D sponsors in order to align incentives that support improved care coordination and better outcomes.

An ACO is a group of health care providers that agree, through contractual and exclusive arrangements, to accept responsibility to care for the health needs of a defined population. The goals of an ACO are to improve the quality of health care outcomes, improve the experience of care, and lower costs. Although, initially conceived as operating in the fee-for-service market for health care services, with the encouragement of CMS and others, some ACOs are transitioning to monthly population-based payments and may eventually assume full insurance risk.

We believe ACOs that transition to assumption of full insurance risk will need to adopt structures and management systems similar to other managed care entities. In order to establish and maintain controls on utilization, quality, and costs, risk-assuming ACOs will likely rely on restricted networks for hospital services, referral physicians, laboratory and imaging services, and pharmacy. This certainly has been the trend for managed care

entities, and limited provider networks appear to be the model of choice for most plans currently offered in the ACA-generated health insurance marketplace.

The recently proposed Medicare Part D rule, CMS-4159-P, if implemented as proposed without modification, poses a significant barrier to collaboration and the development of business relationships between ACOs and Part D sponsors and their downstream partners such as PBMs. The sections from the proposed Part D rule that erect substantial barriers for Part D sponsors seeking to establish innovative and value based relationships with ACOs include the following: (a) proposed limits that undermine (if not totally eradicate) the ability of Part D sponsors to establish and use preferred pharmacy networks, (b) significant restrictions on the use of value based incentives that encourage beneficiaries to choose a lower-cost pharmacy to fill their prescriptions, and establish price ceilings and floors, (c) major changes to regulation of mail service cost-shares that significantly limit the ability of plans to provide cost-efficient incentives for enrollees to select to receive prescriptions at mail; and (d) additional major limitations on the terms and conditions Part D sponsors can stipulate for pharmacy networks. The CMS-proposed modifications to the Medicare Part D program will increase program costs, lower quality, and reduce beneficiary access to drug plans with lower premiums and cost sharing. This is not an appealing scenario for an ACO contemplating the assumption of overall insurance risk for Parts A, B, and D or even seeking to test innovative arrangements with various Part D stakeholders.

If, in fact, CMS wants ACOs and Part D sponsors to work together on building the capacity to get on top of total Medicare expenditures through effective integration of Parts A, B, and D, then CMS needs to review its proposed Part D modifications through this lens. PCMA strongly believes that CMS is working at cross purposes given the disparity between the excellent work of CMS' Center for Innovation and the proposed major overhaul of the Medicare Part D program.

We appreciate your consideration of our comments and look forward to continuing to work with CMS on innovative measures designed to improve the operation of the Medicare program. We have also submitted comments to: http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/

Sincerely,

Wendy Krasner

Wendy Krasner
Vice President, Regulatory Affairs

PhRMA

February 28th, 2014

Patrick Conway, MD
Deputy Administrator for Innovation and Quality CMS Chief Medical Officer
Centers for Medicare & Medicaid Innovation
7500 Security Boulevard
Baltimore, MD 21244

Re: Center for Medicare and Medicaid Innovation Request for Information: Evolution of ACO Initiatives

Dear Dr. Conway:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to respond to the Center for Medicare and Medicaid Innovation (CMMI) request for information (RFI) regarding the evolution of accountable care organization (ACO) initiatives at the Centers for Medicare & Medicaid Services (CMS or Agency). PhRMA is a voluntary, non-profit organization representing the nation's leading research-based pharmaceutical and biotechnology companies who are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

PhRMA supports CMMI's interest in improving care coordination for Medicare beneficiaries – particularly those enrolled in Original Medicare, which traditionally has lacked the infrastructure and incentives for effective coordination across the health care spectrum. Through rigorous assessment and public reporting of quality and health outcomes under various models, CMMI can help drive further improvement in outcomes and efficiency.

ACO efforts underway (both the Pioneer ACOs and the Medicare Shared Savings Program) show promise for overall improvements in patient care and outcomes with potential for longer term savings. PhRMA strongly favors connected, patient and provider-centric approaches to payment reform found in ACO and Medical Home models as compared to efforts to bundle payments for discrete episodes of care, which may fail to account for the full range of a patient's needs across conditions, or differences in severity of clinical need, local practice patterns, and advances in technology.

We recognize the Agency's interest in increasing financial risk for ACOs as early as 2015, either with or without more extensive integration of Part D benefits. This would be a significant change to efforts currently underway, at a time when little is known publicly about ACOs' performance on critical quality measures or their impact on beneficiary outcomes. PhRMA urges CMS to proceed with care; adopting aggressive changes to the ACO model could have negative quality and beneficiary impacts and cause potential harm to other areas of Medicare (e.g. Part D and Medicare Advantage) or the broader health

care market. It is unnecessary for ACOs to assume risk for Part D expenditures, for example. There are opportunities under the existing framework for improved coordination between Part D plans and ACOs.

PhRMA's detailed comments and questions in response to the RFI are included below. Our response is predicated on a set of principles, which we believe should guide the evolution of ACOs in the Medicare marketplace:

1. ACOs should continue to be a distinct financing and service delivery model, offering a unique choice that is meaningfully different from other Medicare options (*e.g.* fee-for-service or Medicare Advantage).

2. An ACO should not bear full risk unless and until it has demonstrated readiness to do so as evidenced by the ability to meet licensure and patient protection requirements required of other full risk-bearing entities in Medicare.

3. ACO requirements and incentives should be flexible enough to permit varied approaches that reflect local differences in practice patterns, available providers, infrastructure and other factors.

4. The evolution of ACOs must not undermine the successful Part D program or key factors in the program's success: competitive bidding, benefit flexibility and beneficiary choice.

5. As ACOs evolve, CMS should assure access to a range of clinical interventions, including new treatments and technologies, and should safeguard against approaches that could lead to undue reduction in beneficiary choice of providers, health plans or treatments.

We appreciate CMMI's request for stakeholder input on this important topic and look forward to working with you as you explore changes to the ACO program.

Sincerely,

Lisa Joldersma, Vice President
Policy & Research, Public Programs

Michelle Drozd, Senior Director
Policy & Research

Detailed Comments on CMMI Request for Information: Evolution of ACO Initiatives at CMS

PhRMA respectfully submits the following feedback on key discussion themes outlined in the RFI:

Section II. A. Transition to Greater Insurance Risk

If CMS chooses to move ACOs in the direction of assuming more risk, it should do so on a gradual basis to help ensure entities have the necessary infrastructure to bear risk and manage care. The ACO program today is relatively new and participation is broad, with more than 350 MSSPs and Pioneer ACOs serving more than 5 million beneficiaries.

The underlying infrastructure and capacities of these ACOs are still in their early stages of development. Beneficiary, provider and community understanding of the ACO model is not yet developed. Capacities and a broader understanding of the ACO model must be developed and nurtured to enable future success.

The dangers of transitioning too aggressively to increased ACO risk are real. Less rigorous oversight of at-risk ACOs could cause broader disturbance to the health care market. In the late 1990s, a lack of appropriate safeguards for capitated providers resulted in a period of significant instability in the private sector, which led to the failure of a number of physician organizations that had assumed greater financial risk.[1] We urge CMS to move with caution in this area.

More specific considerations for moving the ACO model to greater insurance risk are outlined below.

Preparing ACOs to Accept Additional Risk

Many ACOs are in need of additional infrastructure to be successful and fulfill *current* MSSP or Pioneer program requirements. Infrastructure needs will grow as the models develop, begging the question: How quickly can the ACO models evolve relative to growth in infrastructure needs under a fuller risk bearing model? CMS should consider whether conducting additional analyses about the current ACO programs would help inform whether and how ACOs should proceed to accepting additional risk.

PhRMA sees a number of policy challenges to ACOs accepting full insurance risk. Notably, Pioneer ACOs were conceived for providers "with experience operating as ACOs or in similar arrangements;" the model was designed to offer greater opportunities for shared savings than under MSSP.[2] Nine of the original thirty-two Pioneer ACOs decided to leave the program after one year, however. The reluctance of these comparatively more experienced ACOs to pursue full risk or even continue with shared risk raises significant questions about whether providers themselves believe they currently have capacity and infrastructure necessary to manage full risk.

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[1] JC Robinson and EL Dolan. Accountable Care Organizations in California: Lessons for the National Debate on Delivery System. Integrated Healthcare Association White Paper. 2010.

[2] In year three of the Pioneer ACO program, those with demonstrated savings can transition to population-based payments including full risk. Centers for Medicare and Medicaid Services. *Pioneer Accountable Care Organization (ACO) Model Program Frequently Asked Questions.* Available at: http://innovation.cms.gov/Files/x/Pioneer-ACO-Model-Frequently-Asked-Questions-doc.pdf. Accessed February 21, 2014.

This suggests CMS might create additional infrastructure requirements for ACOs interested in taking additional risk, to enable better management of patient treatments in order to meet financial and quality targets. For example, CMS might consider requiring an ACO to demonstrate compliance with clinical criteria for certification as a patient-centered medical home and ability to provide comprehensive medication management services to patients.

In addition to infrastructure and readiness considerations, there are several questions CMS should consider as they determine whether and how to transition ACOs to more financial risk. For example, can ACOs accept more financial risk without accelerating market consolidation; and is it possible to avoid conflicts of interest in the marketplace when providers take on financial risk directly from Medicare through an ACO but also participate in Medicare Advantage networks?

Medicare Advantage – an Existing Full-Risk Option

Medicare Advantage already offers a viable option for providers or insurers to assume full financial risk for the care of Medicare beneficiaries. It would be unwise to create another, different option for provider participation in Medicare as a full risk entity. Creating such a construct would generate incentives for adverse selection and gaming, adding complexity and confusion to the Medicare marketplace and increasing overall Medicare costs.

Should ACOs become eligible to accept *full* risk – which PhRMA opposes – they should first demonstrate readiness and capacity and should be required to meet all licensing, regulatory, infrastructure, financial reserve and enrollment requirements that apply to Medicare Advantage plans. Further, ACOs assuming a greater degree of risk than today, even if not full-risk, should incorporate beneficiary protections, such as a robust appeals and exceptions process for accessing non-ACO providers.

As ACOs evolve, CMS should consider how to assure a fair and competitive market between ACOs and Medicare Advantage. It is important to maintain a level playing field given the substantial number of beneficiaries enrolled in Medicare Advantage plans, some of which are provider-based entities (e.g., Geisinger) that currently are meeting all MA requirements.

Enrollment, Benefit Enhancements, and Limited Provider Networks

To the extent that CMS considers models in which ACOs can prospectively enroll patients or create incentives to influence treatment patterns and/or maintain higher service volume within the ACO's network, it would be appropriate to allow the ACO to make some reductions in cost-sharing for services delivered by ACO providers, albeit in a manner that does not increase Medicare costs. Limited networks and corresponding beneficiary incentives are more consistent with an enrollment model than attribution.

Quality Protections

If ACOs take on increased risk, CMS must improve quality measures and increase attention to beneficiary access. Current ACO quality measures are not sufficient to assure appropriate levels of care even under existing levels of risk. The need for robust quality measures will become even more important if ACOs take on additional risk.

Current, relatively narrow, ACO quality measures track health outcomes for three specific conditions – diabetes, hypertension and ischemic vascular disease – but not for other important conditions. Many ACO patients have conditions for which outcomes currently are not measured. CMS should enhance ACO quality measures by adding metrics to track health outcomes across a broader range of conditions.[3] ACO quality measures should be developed, endorsed, adopted, and updated through a transparent, multi-stakeholder, consensus-based process with real opportunity for input from diverse perspectives.

While there is need to enhance the quality measures in place under current (and future) ACO programs, providers do have strong incentive to perform well on the current, limited measures because ACOs do not receive full shared savings payments if they fail to meet all quality goals. As ACOs move to take on more risk, however, the portion of revenue tied to shared savings – and at least meeting quality requirements – declines. In this case, adding more quality metrics will not be sufficient to protect the quality of care received by patients. If CMS decides to move away from shared savings for ACOs, it should consider how to maintain similarly strong quality incentives in addition to more measures, to ensure that patient access and quality of care are not diminished in the ACO's efforts to reduce costs.

CMS will need additional analytic tools to determine if there are inappropriate shifts or outliers in treatment patterns that may indicate access or quality problems. This type of analysis will become more important if more advanced ACO models permit benefit differentials or restricted networks.

Transparency and Rigorous Evaluation

As ACOs continue to evolve in Medicare, we recommend that CMS take steps to assure there are opportunities for meaningful public comment at the federal level. It is important that CMS work with all stakeholders – including the private market – to assure clear and widespread understanding of the benefits and drawbacks under existing ACO initiatives (Pioneer program and Medicare Shared Savings Program) and any new models under consideration. Greater transparency from CMS regarding measures, evaluation and performance will improve the quality of stakeholder feedback as initiatives progress. The breadth and compressed timeframe for this RFI may work to reduce effective opportunity for input.

To improve transparency of its work going forward, we urge CMS to issue further guidance outlining key principles for ACO development and the ideal interaction between ACOs, Medicare Advantage, and Part D. Such guidance should include key details of models under consideration, including:

- Each statutory provision proposed to be waived for a demonstration;
- How a demonstration will operate under the waiver;
- Statutory authority for the waiver; and,
- The policy rationale for the waiver.

Considering the tight connections between healthcare delivery and payment (whether Medicare, Medicaid or commercial), it also is essential that any effects of ACO reforms on provider consolidation and market power be tracked and evaluated.

[3] When a full endorsed measure is not available, CMS should track a proxy measure focused on quality of care, until an appropriate outcome measure is developed.

Ongoing monitoring of the impact of ACOs on beneficiary access to needed services also is critical. CMS should specify its proposed approach to monitoring, which should include both routine analysis of claims and other relevant data, results on quality measures, and processes at the state and federal level for meaningful beneficiary feedback. To improve the value of demonstrations and their ability to inform future policy making, a careful evaluation process is critical. We strongly recommend that CMS issue guidance regarding its approach to evaluation, including necessary data elements to capture and procedures for timely establishment of a comparison group to control for outcomes associated with any new ACO model. Such evaluations should include a separate assessment of the impact on Part D. Methods of evaluation that rely fully on comparison of outcomes pre- and post-intervention are unlikely to be sufficient to establish causal relationships and meet widely accepted standards of evidence.

Section II. B. Integrating Accountability for Medicare Part D Expenditures

Medicare Part D provides comprehensive and affordable coverage to millions of Medicare beneficiaries. Part D has a strong track record of success and has demonstrated that it provides high beneficiary satisfaction and good access to medicines in a competitive system that has kept costs far below initial projections. Research shows that this success is also translating into reduced rates of hospitalization and other medical spending in Medicare Parts A and B.[4]

It is critical that new options to give ACOs greater accountability for Part D expenditures be designed carefully to preserve beneficiary choice and avoid either undermining the successful Part D program or inadvertently increasing Medicare costs. We believe opportunities already exist to test greater collaboration between ACOs and stand-alone PDPs and we urge the Agency to consider these options as an initial step. To the extent that ACOs take on accountability for Part D benefits and expenditures, they should meet all Part D requirements.

We also note that a recent study which asked ACOs to self-assess their readiness to manage medications found the majority of ACOs were prepared to complete *some* medication management tasks (e-prescribing; integration of medical and pharmacy data), significant gaps were reported in other areas (notifying physicians when a prescription is filled; edits to avoid duplicate therapies or polypharmacy).[5] This suggests that if CMS proceeds, it be judicious in selecting which ACOs to hold accountable for Part D.

ACOs with Accountability for Part D Should Meet All Part D Requirements

If CMS plans to test integrating accountability for Part D in ACOs, prescription drug coverage must be delivered under Part D rules. To assure the same level of beneficiary access to outpatient prescription drugs, ACOs with integrated accountability for Part D should be required to meet all Part D requirements, including those for formularies, pharmacy networks, and benefits. These requirements should not be open to negotiation. If, as seems likely, ACOs are unable to independently meet Part D requirements, they should do so via a contract with a current Part D plan.

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[4] See J.M. McWilliams, "Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage," Journal of the American Medical Association, July 27, 2011 and C.C. Afendulis et al. "The Impact of Medicare Part D on Hospitalization Rates." Health Services Research, August 2011.

[5] RW Dubois et al. "Are ACOs Ready to be Accountable for Medication Use?" *Journal of Managed Care Pharmacy.* Vol. 20, No 1. January 2014.

In particular, we would be very concerned by proposals to create a unified capitation or partial capitation payment for Parts A, B, and D based on national average expenditures, rather than continuing to base payment for Part D on a competitively bid model. Removing the requirement for ACOs (or a contracted Part D plan) to submit competitive bids would undermine the success of the Part D bidding process and the competition that has helped make the program so successful, creating unintended Part D consequences that would swamp any potential gain for ACOs. CMS has noted that the Part D bidding process is designed to incentivize plan sponsors to bid as low as possible in order to garner as many beneficiaries as possible.[6] Approaches to exempt ACOs would undermine the bid process and could change the market dynamics in the program, both of which risk generating disruption and unpredictability for Medicare beneficiaries who depend on Part D.

Similarly, we would be concerned by attempts to require ACOs to take on financial accountability for Part D expenditures while at the same time, a Part D plan continues to be fully at risk for these expenditures. This would result in two separate organizations having incentives to reduce Part D spending, resulting in significantly greater incentive to reduce Part D costs than Parts A or B as well as opportunities to "game" two sets of rules which could increase Medicare costs. These duplicative incentives to reduce Part D spending would be in conflict with published evidence demonstrating that medicines are underused much more often than they are overused[7] and with the recognition that increasing adherence to medications reduces medical spending for a broad range of conditions including hypertension, diabetes, congestive heart failure, and dyslipidemia, chronic obstructive pulmonary disease and osteoporosis.[8]

Analyze Collaborations Underway to Assess Current Barriers to Collaboration

As a first step, CMS should undertake an evaluation of current collaborations between ACOs and PDPs, as it indicated it would do in recent Call Letters. To date, PhRMA is not aware of such an evaluation being undertaken or completed. The results of such an analysis should be made publicly available as part of any Agency effort to give ACOs additional incentives to collaborate with Part D plans. The evaluation could also help pinpoint barriers that ACOs may face in developing such partnerships.

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[6] 73 Fed. Reg. 18,176, 18,179 (Apr. 3, 2008).

[7] W. Shrank et al, "The Quality of Pharmacologic Care for Adults in the United States." *Medical Care*, Oct 2006 and T. Higashi et al. "The Quality of Pharmacologic Care for Vulnerable Older Patients." *Annals of Internal Medicine,* May 2004.

[8] See, for example J.E. Bailey, et al, "Antihypertensive Medication Adherence, Ambulatory Visits, and Risk of Stroke and Death." Journal of General Intern Medicine, 2010; A. Jha, et al, "Greater Adherence to Diabetes Drugs is Linked to Less Hospital Use and Could Save Nearly $5 Billion Annually" Health Affairs, 2012; M.C. Roebuck, et al. "Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending." Health Affairs, Jan 2011; B. Stuart et al. "Impact of Maintenance Therapy on Hospitalization and Expenditures for Medicare Beneficiaries with Chronic Obstructive Pulmonary Disease." American Journal of Geriatric Pharmacotherapy, Oct 2010; R. Halpern et al. "The Association of Adherence to Osteoporosis Therapies with Fracture, All-Cause Medical Costs, and All-Cause Hospitalizations: A Retrospective Claims Analysis of Female Health Plan Enrollees with Osteoporosis." Journal of Managed Care Pharmacy, Jan/Feb 2011.

Data-Sharing to Support Better Medication Management

Building on the findings of the above analysis, CMS could test collaborations in which CMS, an ACO and a PDP or multiple PDPs share data for Parts A, B and D to help more effectively manage patient medications and overall health. Currently, both ACOs and PDPs may be providing medication management without access to comprehensive data about the patient's current medications and treatment plan. Improved ability to share data and the availability of a real time information on medications could prevent unnecessary administrative burden for both ACOs whose patients are enrolled in a large number of Part D plans, and vice versa. An analysis of current collaborations with Part D plans and ACOs could also provide insight into ways for PDPs to work in tandem with ACOs in implementing their medication therapy management programs.

Potential to Remove Barriers to ACO-PDP Collaboration

CMS might consider working with stakeholders to test ways to align incentives between ACOs and Part D plans on a limited scale to manage pharmacy benefits and provide quality patient care. For example, ACOs with significant accountability for Part A and B expenditures might be allowed to enter into contractual relationships with Part D plans to coordinate care, share data, and test joint risk arrangements. The ACO could negotiate with one or more Part D plans to establish terms of the relationship, perhaps including preferred terms for enrollment in a preferred PDP (such as preferential cost sharing) and shared accountability for providing MTM services.

Such arrangements should not foreclose the beneficiary's option to enroll in a Part D plan of their choice. Allowing ACOs and Part D plans to share savings resulting from improved use of medicines – and allowing ACOs to influence a beneficiary's choice of Part D plan – is only feasible and fair in an approach that relies on explicit opt-in by ACO members. As a result, for any such arrangements to be successful, they would require that the ACO already be actively enrolling beneficiaries and working to provide comprehensive care management services. This type of contractual arrangement is inconsistent with an enrollment attribution model in which beneficiaries do not know they have been attributed to an ACO.

Concern about potentially violating certain fraud and abuse rules may dampen ACOs' interest in partnering with Part D plans. Yet such arrangements could help ensure optimal medication use by beneficiaries. More specifically, an arrangement under which an ACO incentivizes a Part D plan to help reach therapy goals, such as reduced blood pressure or HbA1c, through better management of patients' medications could increase the ACO's shared savings by reducing hospitalizations and emergency room visits, but also increase spending on Part D medications. Uncertainty as to whether or not such an agreement would violate the anti-kickback statute may cause ACOs to err on the side of caution, thereby missing an opportunity for better patient outcomes. To address such concerns, CMS should consider setting out explicit rules to allow constructive collaborations by establishing one or more waivers or using existing waivers for this type of ACO-Part D plan collaboration, or modifying an existing waiver.

CMS should remain vigilant about any shifting of Part B costs to Part D by ACOs in an effort to meet savings targets. For example, ACOs might consider compensating a Part D plan for some of the resulting cost to gain support from the PDP for this type of cost-shifting. We do not believe that this type of arrangement would be permissible under current statute and regulations and encourage CMS to continue to generally prohibit this type of arrangement as it considers approaches aimed at promoting ACO and PDP collaboration.

Preserving Long Term Choice in the Part D Marketplace

It will be important that CMS consider how the evolution of ACOs will affect the future Part D and Medicare Advantage market place and the range of choices available to beneficiaries. In markets where there are multiple competing ACOs, development of relationships between ACOs and Part D plans may not significantly affect the competitive dynamics of the market; however, in markets with very dominant provider systems, it is possible that arrangements between PDPs and ACOs could disrupt the market and result in reduced plan choices.

Section II. C. Increasing Accountability for Medicaid Care Outcomes

PhRMA supports continued discussion about how to improve care coordination for dually eligible people and believes that ACOs may have a role to play in such efforts in the future. However, at this time, given the challenges and complexities already inherent in transitioning to greater financial risk for Medicare expenditures, it seems premature to explore adding Medicaid risk.

It would be useful to better understand the potential federal savings from better care coordination before beginning to address how potential savings would be shared by the federal and state governments should ACOs take on accountability for Medicare and Medicaid expenditures. We note that leading health services researchers found that in 2011 federal funds accounted for 80 percent, or $257 billion, of the total spending on care for dual eligible persons. More than two-thirds of total spending on dual eligible persons flowed through Medicare.[9] Medicare's dominant role in funding care for dual eligibles and the existence of programs in Medicare already designed to meet duals' needs indicate that Medicare is the most appropriate axis around which to organize coordinated care for duals.

Summary

The Agency and private sector have devoted significant time and resources to "standing up" the Pioneer ACO effort and first round of the Medicare Shared Savings Program (MSSP). To increase the likelihood that these investments yield favorable returns in terms of quality and efficiency, CMS could consider building on one or both initiatives, creating a "glidepath" for ACOs interested in taking on greater risk and/or greater accountability for Part D expenditures. Private market arrangements between insurers, plan sponsors, and ACOs could be instructive in identifying key milestones.

A glidepath could build on the Pioneer ACO model and include design modifications such as enrollment; increased risk; flexibility to amend the Medicare benefit design to incent behavior, with or without an established provider network; or enhanced care management and coordination with Part D plans. Above all, as ACOs evolve, efficiencies in health care delivery should not come at the expense of quality patient care. CMS should assure access to a range of clinical interventions, including new treatments and technologies, and should safeguard against approaches that could lead to undue reduction in beneficiary choice of providers, health plans or treatments.

[9] Feder, Judy, Lisa Clemans-Cope, Teresa Coughlin, John Holahan, and Timothy Waidmann. "Refocusing Responsibility For Dual Eligibles: Why Medicare Should Take The Lead. The Urban Institute. October 2011

Planned Parenthood Federation of America

Planned Parenthood Action Fund

February 28, 2014

VIA ELECTRONIC SUBMISSION

Director Patrick Conway, MD, MSc
Center for Medicare and Medicaid Innovation
Centers for Medicare & Medicaid Services
Department of Health and Human Services

RE: Request for Information: Evolution of ACO Initiatives at CMS

Dear Dr. Conway:

Planned Parenthood Federation of America ("Planned Parenthood") and Planned Parenthood Action Fund are pleased to submit these comments on the Center for Medicare and Medicaid Innovation (CMMI) *Request for Information: Evolution of ACO Initiatives at CMS*, on the current Pioneer ACO Model and new ACO models that encourage greater care integration and financial accountability. As a trusted women's health care provider and advocate, Planned Parenthood strongly supports CMMI's ("Innovation Center") efforts to actively seek input from a broad array of stakeholders from across the country. Planned Parenthood welcomes the opportunity to comment on how innovative models of payment and service delivery can be designed to reduce health care expenditures while preserving patient access to high quality health care.

Planned Parenthood is the nation's leading women's health care provider and advocate and a trusted, nonprofit source of primary and preventive care for women, men, and young people in communities across the United States. Every year, Planned Parenthood's more than 700 health centers provide affordable birth control, lifesaving cancer screenings, testing and treatment for sexually transmitted infections (STIs), and other essential care to nearly three million patients. Planned Parenthood is committed to improving access to quality, affordable health insurance coverage and care. The Accountable Care Organization (ACO) model is designed as a payment and delivery system reform that requires health care providers to agree to share responsibility for the quality, cost, and coordination of health care for a defined population of patients. As part of the Affordable Care Act (ACA), the Innovation Center is charged with testing ACO models. Consequently, ACOs are likely to be an important part of the future of health care in this country.

We believe that health care delivery systems must meet the needs of women and provide access to critical reproductive health services. In particular, it is critical that Medicaid programs meet the needs of women given that nearly three-quarters of adult Medicaid enrollees are women of reproductive age and the Medicaid

expansion is projected to provide coverage to an additional 4.6 million women of reproductive age. Thus, our following comments on the Innovation Center's RFI focus on how ACO development in Medicaid programs can improve health care access for women's health services and reproductive health care.

Integrating accountability for Medicaid Care Outcomes

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

We commend the Innovation Center for seeking input on state responsibility in developing and implementing ACOs. Regarding the role a state should play in supporting model design and implementation, we believe each state should play a substantial role in designing, developing, and implementing Medicaid ACOs so that ACOs function seamlessly within the state's Medicaid program. To that end, states must ensure that ACOs meet the needs of women by providing enrollees access to all Medicaid-covered women's health services and a wide range of women's health providers. Likewise, we urge the Innovation Center to carefully evaluate Medicaid ACO proposals to ensure they comply with critical federal protections that ensure access to family planning providers and a full range of women's health services.

A. *States must ensure that ACOs provide enrollees access to Medicaid-covered services, including women's health services.*

As the Innovation Center develops ACO models for Medicaid populations and encourages states to implement Medicaid ACOs, states must ensure that ACOs follow federal law and provide each enrollee access to important, covered women's health services in a timely manner. Specifically, states must ensure that Medicaid ACOs provide access to family planning and pregnancy-related services, including abortion in the instances when continuing a pregnancy would endanger the life of a woman or when the pregnancy resulted from rape or incest.[1] Moreover, if the state designs an ACO for the newly eligible population, the state must also ensure that the ACO provides the services outlined in the alternative benefit plan (ABP), including the Essential Health Benefits, which provides coverage for critical women's preventive health services and maternity care. In addition, ACOs must follow federal cost-sharing requirements and exempt family planning services, women's preventive health services, and pregnancy-related services from cost-sharing.[2]

B. *States should ensure that ACOs include women's health providers, who have the expertise to meet the unique needs of women.*

One of the main objectives of ACOs is to enhance continuity of care and access to essential health services as a means of improving health outcomes and reducing program expenditures. To achieve this goal, in developing guidelines for new ACO initiatives, the Innovation Center and states must work together to ensure that the network of health care organizations and providers in each ACO ensures access to women's health providers offering primary and preventive care that meet the health care needs of women, such as family planning services and pregnancy-related care.

[1] States that provide state-only coverage for abortion beyond what is allowed for under federal law should also ensure ACO-enrolled Medicaid beneficiaries receive the same access to abortion as other Medicaid enrollees.

[2] 42 U.S.C. §§ 1396o(a)(2)(B) and (D), 1396o(b)(3)(B)(vii); 42 C.F.R. §§ 147.130(a)(1)(iv); 447.53(b)(2) and (5); 447.70(a)(7); 78 Fed. Reg. 42160, 42307 (Jul. 15, 2013) (to be codified at 42 C.F.R. § 440.347(a)).

Within the Medicaid context specifically, states must ensure Medicaid ACOs meet network adequacy requirements, including direct access to women's health specialists.[3] In addition, we urge the Innovation Center and states to reinforce that Medicaid ACOs must provide enrollees freedom of choice for family planning providers. For example, we appreciate that CMS ACO initiatives have a goal to "[c]ontinue to preserve beneficiary freedom of choice in FFS Medicare," and we urge the Innovation Center to extend that goal to ACOs operating within the Medicaid program.

Existing federal law and policy unequivocally protects an enrollee's ability to receive family planning services from any qualified Medicaid provider – not just those providers in a certain network.[4] Indeed, CMS has explicitly stipulated that a "recipient may obtain family planning services and supplies from outside of the HMO without an HMO referral, even if the HMO contracts with Medicaid to provide the same services."[5] Freedom of choice for family planning has been instrumental in guaranteeing timely access to family planning services, which in turn, has improved the health and lives of women and their children. Therefore, at a minimum, states must afford enrollees in a Medicaid ACO the same protections – and the same access to services and providers – as other Medicaid enrollees.

Ensuring meaningful access to women's health providers in ACOs is especially important because of the unique access issues women already face and the reality of how women experience the health care system in the United States. Women's health providers serve as an entry-point into the health care system and as an ongoing source of care for millions of Americans. In fact, six in ten women who receive care from a women's health center like Planned Parenthood consider it their main source of care. An estimated four in ten women consider these providers their *only* source of care,[6] underscoring that ACO models must include women's health providers in order to truly capture the reality of women's health care access in the ACO model.

New research also shows that women access health care and experience the health care system in unique ways – developing strong relationships with their OB/GYN providers and turning to OB/GYN providers as their main source of care.[7] In fact, this new research shows that half of women ages 18-44 say they are more likely to see their OB/GYN provider on a regular basis than any other type of provider. Almost 6 in 10 women (58 percent) report seeing an OB/GYN provider on a regular basis, and one-third of women (35 percent) view their OB/GYN provider as their main health care provider. Notably, OB/GYN providers play an even stronger role in providing health care for low-income women and women of color. Low-income women (41 percent) and Latinas (47 percent) are far more likely to say their OB/GYN provider is their main source of care, and 64 percent of African-American women say they see an OB/GYN provider regularly, compared to 58 percent of women overall.[8] To truly address and improve continuity of care, ACO models and guidelines must reflect women's unique and ongoing relationship with OB/GYN providers.

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[3] 42 C.F.R. § 438.206(b)(2).
[4] 42 U.S.C. § 1396a(a)(23)(B); 42 C.F.R. § 431.51(a)(4).
[5] CMS, State Medicaid Manual § 2088.5.
[6] Guttmacher Institute. *Specialized Family Planning Clinics in the United States: Why Women Choose Them and Their Role in Meeting Women's Health Care Needs*. (Nov. 2012), available at: http://www.guttmacher.org/pubs/journals/j.whi.2012.09.002.pdf.
[7] Planned Parenthood and American College of Obstetricians and Gynecologists (ACOG) conducted research to better understand the close relationship between women and their health care providers. This study, the first of its kind since 1996, is based on six focus groups and a national survey of over 1,000 women ages 18-44 conducted in July 2013. PerryUndem Research & Communication. "Women & OB/GYN providers." Research conducted for Planned Parenthood Federation of America, November 2013.
[8] *Id.*

Moreover, women's health providers offer services tailored to the needs of women and offer appropriate expertise to meet their medical needs, making it even more critical to ensure women's health providers are included in ACOs. Specifically, new research found that the services that women say they needed most over the last two years, such as an annual well-woman exam, birth control, pre-natal care, and a pap test, are exactly the services provided by women's health providers.[9] Also, OB/GYN providers are more likely to council women about important preventive health care; these providers are two times more likely than other health care providers to talk to their patients about HIV and birth control.[10]

New ACO models should reflect the realities of how women experience the health care system and the significant and primary role OB/GYN providers have in a woman's life – in addition to meeting the minimum federal and state Medicaid standards. Therefore, we urge the Innovation Center to issue guidelines for new ACO initiatives, which requires, in part, that states ensure ACOs include women's health providers, including family planning clinics.

C. *States must ensure that ACOs do not discriminate against providers or individuals seeking services.*

ACOs are designed with the intent to prevent gaps in health care access and improve access to health care by coordinating patient care between providers. Yet this important goal may not be realized without strong non-discrimination protections for ACO providers and enrollees. Accordingly, we urge the Innovation Center to develop strong model non-discrimination protections for states that would: 1) prohibit ACOs from impeding an enrollee's access to covered services; 2) prohibit any attempt to exclude women's health and family planning providers from participating in ACOs; and 3) ensure that the refusal of an individual provider or individual health care entity does not impact other ACO-participating providers from furnishing needed covered services, including the full range of women's health care and reproductive health care services.

In order to ensure ACO enrollees have access to all covered services, including reproductive health care, states should ensure that ACOs are seamlessly integrated into the broader Medicaid program such that an enrollee can access another Medicaid provider in a timely manner if no provider within the ACO is willing or able to provide a covered service. Additionally, the state must ensure enrollees have access to clear information about which services are and are not available through a particular ACO network, as well as information for the out-of-network providers that will provide such services. Without these critical protections in place, a woman may not be able to receive the full information or health care necessary to protect her health and wellbeing.

D. *If the Innovation Center collaborates with other agencies to develop ACOs as a part of other coverage programs, it must ensure that individuals have access to all covered services, including reproductive health care, and that ACOs guarantee access to women's health care providers.*

As the Innovation Center and states collaborate in the future, states may wish to implement ACO models as part of the Basic Health Program (BHP) or "Bridge Plan" options in the state. The BHP and Bridge Plan options are important tools for states to streamline continuity of coverage and care for many low-income individuals and families. Such programs to improve continuity of coverage may be effectively coupled with ACO models as a way to further streamline and integrate care systems.

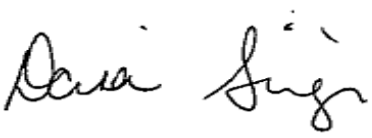
[9] *Id.*
[10] *Id.*

To truly achieve the goal of integrated care systems, the Innovation Center must incorporate standards to make sure consumers in BHP Plans or Bridge Plans using ACOs have access to all covered services, including reproductive health care, and timely access to a broad range of providers, including family planning and OB/GYN providers. To do so, as the Innovation Center works with HHS and states to incorporate ACOs into the BHP and Bridge Plans, the Innovation Center must ensure that ACO model guidelines include Essential Community Provider (ECP) protections and the accompanying non-discrimination standards, which are critical to ensuring patient access to the trusted providers in their communities. Likewise, the Innovation Center must make clear that ECPs that are in-network in BHP and Bridge Plans must be able to participate in ACO arrangements.

BHP and Bridge Plans are important elements of the ACA's coverage expansions because these programs are designed to reduce coverage gaps and improve continuity of care for many low-income individuals and families whose income fluctuates and who may move between the Marketplace and Medicaid. However, if there are not enough health care providers available to consumers, newly-insured enrollees may be left without the basic care they need. Incorporating the ECP standards as part of ACO initiatives in the BHP and Bridge Plan programs could both ensure access to essential providers and better enable individuals that churn in and out of the BHP and Bridge Plans to maintain continuity of care.

Planned Parenthood looks forward to working with the Innovation Center on our shared goal to improve access to quality health care through the development of alternative health care payment and delivery models. We thank you for the opportunity to provide these comments. If you have any questions, please do not hesitate to contact me at 202-973-4800.

Respectfully submitted,



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PREMIER TRANSFORMING HEALTHCARE TOGETHER®

March 1, 2014

Dr. Patrick Conway
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RE: Request for Information: Evolution of ACO Initiatives at CMS.

Dear Dr. Conway:

On behalf of the Premier healthcare alliance, a healthcare improvement company uniting an alliance of more than 2,900 U.S. hospitals and nearly 100,000 other providers to transform healthcare, we appreciate the opportunity to comment on the Request for Information: Evolution of ACO Initiatives at CMS. Premier, a 2006 Malcolm Baldrige National Quality Award recipient, maintains the nation's most comprehensive repository of hospital clinical, financial and operational information and operates one of the leading healthcare purchasing networks. Premier is dedicated to working with our member hospitals to continue to make healthcare safe and effective as evidenced through our Partnership for Care Transformation (PACT) collaborative, the largest population health collaborative in the country. Our comments, attached, primarily reflect the concerns of our owner hospitals and health systems that are part of PACT.

Should you have any questions about our comments, please do not hesitate to contact myself or Danielle Lloyd, vice president, policy development and analysis, at 202.879.8002 or danielle_lloyd@premierinc.com.

Sincerely,

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RFI: Evolution of ACO Initiatives at CMS

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. The Pioneer ACO Model

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model?

No

1A. Why or why not?
Most of the MSSP participants with whom we work are not currently interested in moving into the Pioneer program. There are major reservations that the many required capital and other investments will outweigh the possibility of shared savings. This is due to both the majority of ACOs being at too early of a stage in the program to accurately gauge their ability to take on more risk and that there is not enough trust in the system as of yet to take on risk. This stems from a few major issues: 1) the continued delays in data and reports, as well as an inability to verify or corroborate the data and results 2) the ongoing changes to the quality measurement specifications and lack of clarity on how benchmarks will be set going forward, and 3) the major revisions to the spending benchmarks. While we recognize that some revisions to the benchmarks, or alternatively to the underlying spending, are necessary to account for major policy changes such as sequestration, the major deviations from what was initially estimated makes it very difficult for ACOs to manage their programs. We suggest that such adjustments are confined to significant changes; such as if a Sustainable-Growth Rate bill is passed that dramatically alters physician payments. We are further concerned that we cannot replicate or verify the changes that resulted from the MSSP PY1 Interim renormalization process, and the actual drop in the national FFS absolute value change in per capita expenditures (particularly for the non-disabled aged population). While the rate of FFS spending has slowed, the actual spending has still increased. This suggests that the new, lower risk beneficiaries coming into the program are diluting the pool on a per-capita basis. CMS might consider calculating new and established beneficiaries separately, adjusting for the proportion of new beneficiaries in an ACO's population, or using only an attributed population as described in II. A. 8. A. to ameliorate this artifact. Ultimately, it is not clear that there will be a return on investment for participating in this program, thus most organizations are not willing to take on the existing Pioneer risk structure let alone add additional risk to the system.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?

- Accept all organizations that meet the qualifying criteria

2A. What are the advantages and/or disadvantages of either approach?
While we do not have a large interest from our membership in participating in an expanded Pioneer program, we do recognize the importance of utilizing the model as a means for testing and informing changes to the MSSP. With that in mind, we believe that CMS should accept all qualified applicants. It is important to test these models with as many organizations as are willing and able to ensure the results are as broadly generalizable as possible. Moreover, it will move delivery system transformation faster than arbitrarily limiting the participants.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?
There are several refinements that will further improve the program and foster increased participation. The first adjust would be creating a requirement that the setting of quality and financial benchmarks are complete and publically reported prior to the beginning of the performance year. Currently, the program utilizes a dynamic methodology where the benchmarks are adjusted throughout the performance year. This approach magnifies the challenges for ACOs to set performance goals, and track progress throughout the year.

Actionable, adequate and timely data is critical to the ability of ACOs to manage their populations. To this end, the Innovation Center should work to further enhance the data provided to ACO Pioneers, which we will point out if far more comprehensive than the MSSP participants. Specifically, it should work to provide more complete data to the ACOs, which is delivered in a timelier manner. For example, rather than wholly excluding substance abuse data, CMS could provide it on a de-identified basis. In addition, it would be helpful for ACOs to get consistent reports that reconcile beneficiaries across them and that give per beneficiary per month figures. We understand that currently the reports are generated by different entities/contractors, which leads to discrepancies in the beneficiary numbers across reports. This makes it more challenging to identify high-cost beneficiaries.

A further refinement to the program would be an alteration of the alignment process that would allow for beneficiaries to sign an attestation opting into the program. This would provide organizations an opportunity to utilize semi-closed networks within the ACO. One of the major challenges identified by Premier members that participate in the Pioneer program is the lack of ability to keep the beneficiary within network, and thus control the quality of care provided as well as the cost. This is even more difficult in

areas with heavy MA penetration, as that often skews the population that becomes aligned with the ACO. CMS should allow ACOs that take on insurance risk and have an actively aligned beneficiary population to establish networks by tiering copayments. Beneficiaries would still be able to seek care wherever they so choose, but there would be financial ramifications for going out of network.

The Innovation Center should consider developing an additional model for the Pioneer program with lower levels of risk to bring in more participants. Specifically, the Innovation Center should develop a model where participants would have a corridor where for both losses and savings would be attributed to Medicare. Once an ACO saved/lost beyond that corridor, then it would be responsible for sharing the savings/losses with CMS.

B. Population-Based Payments:

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP?

Yes

1A. Why or why not?
The ability for Pioneer ACOs to accept a population-based payment (PBP) will move the program in the correct direction and will more fully meet the needs of providers to pay for services that are currently not reimbursed by CMS but are necessary to adequately manage the aligned population. Allowing the ACO to select the FFS reduction amount would allow providers to gain experience in taking population-based risk without having to go “all in.” Particularly for ACOs that are comprised of non-employed providers, allowing for a gradual movement to population-based payments will ensure that the ACOs do not get ahead of their ACO participants. Forcing Pioneer ACOs to accept between 50 and 100 percent of their expected Part A & B revenue in PBPs could force ACOs to move too quickly, without the experience necessary to be successful in that type of model.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?

Yes

2A. Why or why not?
Generally speaking, we believe that the more inclusive models will be more successful. To this end, CMS should allow suppliers of DME equipment to be included as a

provider/supplier in an ACO. ACOs are already responsible for the Part B spending of their aligned population, and allowing for a DME supplier to become a partner that works hand-in-hand with the ACO will further encourage value-based relationship and a shift the mindset of suppliers towards an accountable model.
However, we are unclear how this would work operationally given the move to DME competitive bidding. It is also unclear whether an ACO could legally have an exclusive contract with a specific DME provider to reduce spending. It may also be difficult for the ACOs to monitor the marketing from DME providers to beneficiaries if they were officially affiliated with the ACO, or whether such a restriction would be seen as not worth it for the possibility of shared savings.

Thus, CMS would have to put out significant guidance governing such additions, and it is not yet clear that ACOs would seek to add the DME organizations.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves?

Yes

3A. Why or why not?
Population based payments (PBP) will create an opportunity for Pioneer ACOs to provide services to beneficiaries that are not traditionally reimbursed by CMS. This will allow providers more flexibility in how they are delivering care, providing for new tools and approaches that could be a vehicle for Pioneers to drive down costs. CMS should change the requirement that a Pioneer ACO generate a specified level of savings in prior performance years in order to be eligible to receive PBPs. Specifically, CMS should allow a Pioneer to receive PBPs if they did not share in losses over the previous performance years. We believe that PBPs will allow greater flexibility that will make it easier for ACOs to achieve savings, even if they did not achieve substantial savings in the year prior. This approach will allow more organizations to receive PBPs, and will set an acceptable threshold so that organizations that are sharing in losses with CMS would not reach an untenable financial situation.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

Yes

4A. Why or why not?
The existing PBP policy assists ACOs in moving toward more risk, but this method is really just prepayment of the underlying FFS payments. If the goal is to move toward insurance risk, then CMS should offer partial/full capitation for subsets of services or a

subset of the population. For example, CMS could capitate primary care services, but leave hospital services under the FFS system with reconciliation against targets. Or, encourage greater use of prospective bundled payments for certain services while maintain the global reconciliation against targets.

Section II: Evolution of the ACO Model

A. Transition to greater insurance risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations?

Yes

1A. What are the potential benefits and risks to the Medicare program and beneficiaries?

To the extent that insurance risk is added to the program it can further serve to unite providers in working together to bring the best value to Medicare and its beneficiaries. However, if providers are not yet ready for this risk, it could disrupt the market and cause unintended negative consequences for beneficiaries. Thus, we urge CMS to proceed cautiously, and to make some key changes to the program to prepare and enable providers to take on such risk. As is stands, our members do not believe it is feasible to take on risk without any of the mitigating levers that MedicareAdvantage (M/A) plans have such as enrollment, narrow networks and differing benefit design. We also note that some areas of the country may not be willing and able to take on risk due to low population density unless major changes are made to the program such as calculating performance over multiple years, pooling risk across ACOs, or significant advances in health information exchanges. Thus, such a risk bearing model should not be compulsory.

Specifically, the ACO model relies on an attribution method to assign beneficiaries. This method results in significant turnover in the population the ACO is accountable for during the year. We commonly hear from members that only about 75% of their population remains the same from one year to the next. A Pioneer member shared with us that there was 40 percent turnover in their population of more than 50,000 lives in year 1 and 33 percent turnover in year 2. We recognize that some of this “churn” is related to other considerations, such as movement to MA or death, but we believe that some sort of enrollment, or hybrid enrollment would greatly diminish this concern. It could be that a portion of the beneficiaries overtly chose to enroll in the model while the balance of beneficiaries is assigned through attribution, which would at least stabilize a portion of the population.

As it stands the underlying fee-for-service benefit structure applies to ACOs without exception. If ACOs were to take on insurance risk, an ability to vary copays depending on services and providers is critical to both improving the quality of care and reducing spending. We further explore this concept in II. A. 10.

If CMS choses to offer an ACO model with insurance risk, it also needs to consider the interrelationship between MA and the ACO program. It may be in CMS' interest to have ACOs in areas with MA plans even if they are paid more per capita, knowing that their spending will continue to trend down and capture a greater portion of the Medicare population than MA. But, it would be disruptive for ACO payments to drop below those of MA in that area as it may then force a shift in these organizations to MA plans where the fee-for-service beneficiaries may, or may not follow them. Moreover, as suggested by some of the questions below, some consideration would have to be given to unifying some of the program requirements.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)
CMS should start with Medicare only before expanding to Medicaid. However, it should include Part D that was only excluded from the underlying programs because of the current structure of the Medicare program. It is not logical or appropriate to exclude Part D from a risk arrangement as it fundamentally affects the rest of the care provided and overall outcomes. However, operationalizing this addition will be very difficult not only for the providers, but for CMS and the states. Thus, all stakeholders will need to come together to determine how best to accomplish this goal and how much time is needed to move efficiently and effectively toward this.

3. Are there services that should be carved out of ACO capitation? Why?
The ACOs should be able to determine which services are included in their capitation as part of their proposal to CMS.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?
The ACOs would need to demonstrate network adequacy similarly to MA if they take on insurance risk, move to an enrollment model, and can vary copays and deductibles based on the providers used and the services furnished per the above comments. This would include all of the services included within the capitation. To the extent that the ACO does not have sufficient representation within its structure, then contractual agreements would be needed with other providers.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What

regulatory and compliance elements in Medicare Advantage would NOT be appropriate for ACOs assuming full insurance risk?
It would make sense to seek alignment between the ACOs that accept insurance risk and MA plans on marketing to ensure beneficiary protections. Requirements around maintaining a compliance officer could also be reasonably applied to such ACOs.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?
State licensure for risk bearing entities can be very onerous and costly, and varies dramatically across states. One member reported that they divested of a plan they had a substantial stake in that covered nearly 40,000 lives because the reserve, reporting and other such requirements were too challenging. States that have a less stringent requirement for organized delivery systems should be used as a model. CMS should also consider a federal alternative licensure for ACOs. This would assist in states that, for example, do not allow for-profit managed care organizations.
We believe that all of the waivers that apply to MA plans should apply to a risk-bearing ACO model. There are some key waivers that are not present in the MSSP program that should be added at minimum, a waiver of the skilled nursing facility three day stay requirement waiver of the home health homebound requirements, an allowance for sharing of internal ACO savings (as opposed to shared savings), in home safety checks prior to procedures, all of the site of service coverage policies that are rooted in the fee-for service system (IRF 60% rule, LTCH 25% rule etc).

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?
Depending on whether the model includes voluntary member alignment, the ACOs would need to enhance their marketing infrastructure. In addition, the ACOs would likely need to augment their member services for scheduling, after hours nurse advice line, and complaint handling. The ACOs would also need to extend their data analytics beyond what they are already doing for performance management to include more risk analytics, physician profiling, and other forecasting. Lastly, TPA-like functions including how to ensure downstream payments are correct such as to critical access hospitals that are not “in network.” While many of the existing MSSP ACOs do not have the ability currently, there are some who already own their own health plans and would be able to easily scale up such functions if they were to move to a risk-bearing model.

8. What are approaches for setting appropriate capitation rates?
It is hard to make sweeping generalizations about how this should work. As noted in II. A. 1. A., however, consideration needs to be given to the relationship between local MA rates and the ACOs. Moreover, it is not clear if CMS means to fully capitate payments in

the sense of a monthly per member per month fee, or if it intends an annual global capitation where fee-for-service is still relied upon for daily payment. Certainly the latter would provide an easier transition to risk for ACOs that have not heretofore had to pay claims to other providers.

8A. The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends?

Milliman reports from their research that attributed populations have higher underlying cost trends than non-attributed populations. This is not surprising as the attributed population is seeking care while not everyone in the non-attributed population is seeking care. Thus the attributed population is not only likely to have higher costs, but also a higher cost trend. According to a Milliman analysis, the difference can be quite large. CMS uses the national Medicare growth trend to grow the ACOs benchmark and calculate savings. This trend includes non-attributable, healthy persons, and is lower than the trend for attributable, sick persons. This puts the ACO at a disadvantage and makes it much harder to achieve savings. CMS, however, could remedy this by using a cohort of attributable persons to establish the national growth trend and thus remove this bias.

8B. What about for using a local reference expenditure growth trend instead?

9. What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

Under MSSP the risk scores for the beneficiaries are capped at a baseline where many beneficiaries' conditions were not captured. Only demographic shifts or net new entrants into the program can increase the risk score. Consequently, the ACOs are more likely to see a reduction in risk, due to their good work improving beneficiary health, than they are to see an increase. While there is a normalization step to account for code creep, MA plans can see an increase in case mix and can retroactively add to a beneficiary's conditions that affect the risk score. This puts ACOs at a disadvantage to MA plans, and decreases their likelihood of achieving savings. If the ACO does not document and code an amputation, for example, each year then the risk score will decrease because there is no opportunity to make corrections.

Rather mimicking the MA method for those MSSP who take risk, CMS should consider new methods. This is a very important area where CMS should continue to devote resources. We are unclear if the Pioneer risk adjustment could be applied more broadly since it is part of a matched cohort methodology. But, at the same time, we need an option that does not use diagnoses if CMS is unwilling to allow that risk to increase over time. Hopefully, CMS will learn from its current testing and be able to develop a risk adjustment method that is even better and can be used in this context.

In addition, MSSP ACOs do not get the HCC risk score by beneficiary. This would be crucial for a risk-bearing entity and would need to be added to the beneficiary basic files. As we understand it, CMS already added HCC scores to the Pioneer data files.

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes?

As it stands the underlying fee-for-service benefit structure applies to ACOs without exception. This precludes ACOs from steering beneficiaries to "in-network" providers, encouraging compliance with physician orders, or selecting lower-cost treatments. If ACOs were to take on insurance risk, an ability to vary copays depending on services and providers is critical to both improving the quality of care and reducing spending. Such flexibility would allow the ACOs to structure the benefits in a way that encourages beneficiaries to seek care that is evidenced-based and at providers of higher value services that will lead to better outcomes. For example, our members have had success under other programs with waiving patient copays for certain medications in order to improve health status and avoid adverse health events from medication non-compliance. If an ACO were to take on Part D risk, such an ability to interject value-based benefit design would undoubtedly be useful.

In order to administer such changes, the ACOs would need an enrolled population rather than an allusive attributed population that does not necessarily even know about the ACO or its work on behalf of the beneficiaries. The Medicare Payment Advisory Commission has been discussing a possible Medigap plan that could be pared with ACOs as a way to alter beneficiary copays. While we are not clear on the details of how this might work, it is worth giving some consideration. Those who purchase the Medigap plan could be enrolled in the ACO for the year, while the rest are assigned via attribution.

It would also serve beneficiaries for the ACOs to receive more legal waivers for providing items and services free of charge that might otherwise be considered an inducement. The ACOs need the flexibility to invest in items or services that do not necessarily have current billing codes, but could have a long-term positive impact on the beneficiaries care. PACE is a model for this where, for example, a program can pay to have a wheel chair ramp installed in the person's home so that they can get out of the house for medical visits, adult day care etc.

10A. How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

Because Medicaid inherently serves lower income patients, lower copays for critical services and free items and services such as transportation are key. If Part D is included, then the use of formularies and copay tiering would be essential to incenting

the use of maintenance drugs while discouraging the use of pharmaceuticals with little evidence of their efficacy over others.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?
With a shift to a risk bearing model, the major concern is whether there will be “stinting” of care. The ACO programs have extensive quality measurement programs to ensure that reduced services are avoiding waste rather than needed care. As the program evolves, so too will the measurement to ensure beneficiary protections.
There might be concern that providers will steer to “in network” ACO providers to reduce costs whether they are of high quality or not. However, this would ultimately work against the ACO as the patients may become more acute, and we believe the quality measurement would identify any demonstrable diminution in the quality of care provided.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?
If an enrollment model is allowed, ACOs would have to accept all beneficiaries who chose the ACOs and meet the eligibility criteria (e.g. not in an MA plan, have both Part A and B coverage etc.) to prevent outreach to solely healthy/low risk beneficiaries.

13. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology?

Yes

13A. What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?
By allowing beneficiaries to voluntarily align with the ACO it will be clear to the ACO who their focus population is and to the beneficiary where they should first be seeking care. The expectation is that the closer relationship will engender a greater loyalty that will then reduce turn over from year to year in the population. A more stable population allows providers to better know and understand the needs of the beneficiaries and use this information to improve care.

B. Integrating accountability for Medicare Part D Expenditures
Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care

coordination and outcomes.

1. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?
Our MSSP participants have not yet developed agreements with Part D plans. However, members are beginning to consider relationships with local retail pharmacies and/or the purchase or retail pharmacies. There is recognition that medication adherence, medication reconciliation and other important issues could assist in reducing Medicare spending under Parts A and B, however, the first wave of this work is being conducted through the primary care sites and at hospital discharge. In the future, once the MSSP participants are more mature, there is likely value in connections between the MSSP and plans. For instance, the plans could alert the MSSP to a missed refill or filled prescriptions that appear to be conflicting in more or a real time basis than ACOs could pick up in retrospective claims data.

1A. What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?
One stumbling block to considering strategies in this area is the inadequacies of the Part D data. Most members are still working on fully understanding the Part D data and how, or even if, it can be used given that the paid amount is blank wherever it was provided through a Medicare Advantage plan. Given this limitation, ACOs would be at a disadvantage in approaching a Part D plan to establish a formal contractual relationship.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?

No

2A. Why or why not?
Given that the MSSP participants have, at most, 21 months of results, it is difficult at present to conceive of imminently adding such a dimension to the program. This is especially true given the limitations of the data. CMS should also consider providing ACOs with Prescription Drug Event data associated with its beneficiaries. Moreover, members are hesitant to take on any risk when they are not yet confident about their performance under MSSP; the beneficiary population is not stable due to the attribution methodology; and there is no ability for the ACOs to narrow networks, alter copays, etc.

2B. If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus

creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?
The MSSP providers do not have experience with the Part D bidding process and thus would be at a distinct disadvantage. Moreover, meeting the state licensure requirements can be both costly and onerous, but it varies dramatically by state. In addition, it would be simpler for both CMS and the providers to have a unified MSSP program with a combined target for Parts A, B and D combined.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures?

No

3A. What other mechanisms would allow ACOs to assume accountability for Part D outcomes?
CMS could also encourage ACOs to partner with PDPs in joint product offerings to ACO beneficiaries (e.g. premium discounts, copay assistance, formulary enhancements/advantages, data sharing, joint effort on prescription/refill reminders and med rec, especially for high risk benes). This could be co-run by the ACO and the PDP so that the ACO does not have to assume full risk but is in a partnership.

C. Integrating accountability for Medicaid Care Outcomes
CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations.

1. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

Yes

1A. Why or why not?
To the extent that ACOs can enter into similar arrangements across payers, the transformation will be faster and more effective. It is in the best interest of the providers, CMS, that states and beneficiaries to bring more populations into similar arrangements. However, this should not be compulsory as there is varying readiness among providers and states to move to such a model. Members report that even in states with state law authorizing Medicaid ACOs and state staff who are knowledgeable, the programs are very complex and getting buy in from the stakeholders and CMS challenging. There cannot be a one size fits all approach applied, so the implementation of joint Medicare/Medicaid ACOs will need to be state by state on a voluntary basis.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? (For instance, should ACOs be accountable for outcomes

among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?).
The addition of the Medicaid program, and which subpopulation, should not be compulsory and should be tailored by state and by provider following a transitional path. It would likely be an easier transition to begin with the dual eligible population as the needs will be very different, for example, in the categorically eligible Medicaid beneficiaries.

While the aspiration of ACOs taking on a whole geographic area is amiable, we are so far removed from that possibility at the moment in virtually all markets in the US. This would require unprecedented cooperation across providers, payers, the public health agencies, schools (depending on the population) and community-based organizations. Per below, in II. D. 1., we note that the population that may be the easiest to move to this even more comprehensive model is the disabled, but even with that population there is extensive ground work that would need to be completed with strong leadership from CMS before such a move.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?
The states must play an integral role in providing appropriate incentives. Firstly, the states must ensure state law supports the models, which may not only require adding new authority under the Medicaid program, but also removing barriers in existing insurance and privacy laws as an example. In addition, the states must gain CMS approval through state plan amendments or other waivers. As part of these efforts, the states will be playing an active part in the design of the programs and what incentives are built in (as well as barriers removed) to encourage providers to enter into new payment models. This will not only benefit the Medicaid program, but the healthcare system more broadly. If CMS provides assistance to the states, it will serve to strengthen the Medicare program as well by allowing providers to more fully commit to the model and care transformation.

3A. What roles should States play in supporting model design and implementation?
While we believe that States should be involved in model design to reflect the unique population served and care patterns in the area, the states are often ill equipped in terms of expertise and capacity. To the extent that CMS could facilitate, the process might move faster. This could be in funds as well as technical assistance. For instance, the State Innovation Model grants have greatly facilitated states in developing alternative payment models that are advancing delivery system reform. In addition,

CMS could assist states in determining the files specifications for the data files the states will need to provide to the ACOs to effectively coordinate/manage care. Finally, CMS could also work with the states to ensure uniform quality measure specifications where the state and CMS chose to measure similar aspects of care.

3B. Do States have adequate resources to support an ACO initiative in collaboration with CMS?

Each state has a different level of expertise and resources to apply to such initiatives and this can be variable across time. Some states are moving ahead with very ambitious programs that we expect will be very successful. However, to ensure that pockets of the country are not left out of this transformation, CMS will need to provide significant assistance and resources to those that have not yet made significant progress.

In addition to providing states with grants and technical assistance to design new programs, CMS could also allow the Medicaid ACOs that may not be part of MSSP join the ACO Learning Network. CMS could also include a learning track geared to those ACOs that have taken responsibility for this population (whether in addition to Medicare or not). Another service CMS could provide to reduce the burden on states is to provide the data extracts to the providers. This would also ensure that the files are similarly constructed to the Medicare data making it easier for the ACOs to make use of the information.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?

Our ACO's do not currently have this capability as it is our understanding per the Data Use Agreement that we are not permitted to comingle Medicare and Medicaid data without explicit approval to do so. Section 10 states, "The User agrees that, absent express written authorization from the appropriate System Manager or the person designated in section 20 of this Agreement to do so, the User shall not attempt to link records included in the file(s) specified in section S to any other individually identifiable source of information. This includes attempts to link the data to other CMS data file(s). A protocol that includes the linkage of specific files that has been approved in accordance with section 4 constitutes express authorization from CMS to link files as described in the protocol." The only exception expressly permitted in the addendum is for the linking to individually-identifiable health information such as the medical record, which we understand to include Electronic Health Records.

If CMS provided Medicaid data and allowed the linking of Medicare and Medicaid data, our ACOs would be able to accept and use the data. At Present, Premier already accepts Medicaid data (that is maintained separately) through its PopulationAdvisor product for members that are currently working with their states on efforts similar to MSSP.

4A. What are the capabilities of providers in integrating this data with electronic health records?
In our experience, many MSSP members are using claims data to conduct all of their population health analytics (e.g. risk stratification, identification of care gaps, etc.); however, perhaps a third of our members are using primarily EHR data to accomplish these same analytics (even though their target group is larger, because it does not consider the attribution method). Of these, a handful will be able to link their EHR data to their MSSP/Pioneer data by this summer through our PremierConnect™ Enterprise Data Warehouse. Specifically this integration is supporting enhanced care through the identification of high risk members, their critical risk factors, and unmet care needs as well as facilitating proactive outreach and care management. While all of them are benchmarking against each other using claims data at present, benchmarking across the ACOs integrated claims and clinical data is forthcoming.

4B. What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?
Our members are working on connecting the hospitals to the physicians and in some cases to Health Information Exchanges; however, there is a lot more to be done in this area. Technology is also enabling many to gather data from beneficiaries at home to avoid visits. But, there is not yet much linking non-traditional care providers with the ACOs at this point other than personal relationships. The ACOs are continuously considering additional ways to connect to the other providers and the community to enhance their work.

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? (Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?)
While unified programs are ideal, we are concerned that it is not practicable from inception. There is such varying resources and expertise across the states, it is not clear that they can all support the same model. For example, it is unlikely that many states will be able to deliver the same level of data as provided under Medicare. Thus, we think it is wise to allow ACOs to choose how they want to structure their financial arrangements.

D. Other Approaches for Increasing Accountability

A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns.

1. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?
While we support the vision suggested by this question, we have such fundamental operational questions and concerns that it is difficult to comment concretely on this option. While there is merit in unifying the payment and quality policies for these currently distinct populations, this would fundamentally change the face of healthcare. Such a model would require not only health systems and community-based organizations to work together in a far more meaningful way, it would also require competing health systems to work with each other. While this is a laudable goal, it is difficult to conceive of upending the fundamental market dynamics in such a way in the near term.

One particular population that some of our members have discussed such an approach in the future is the disabled. Because this population receives such significant public funding from many different state and federal agencies, the need/urgency to move to such a model is greater. While the operational challenges would remain, there is an increased likelihood of getting disparate providers and other organizations coalesced around similar goals in the near term.

1A. What are the most critical design features of a provider-led community ACO model and why?
The return on investment would need to be clear through the structure of the model especially if the model includes risk. It would need to include protections to ensure that the providers/organizations that are contributing the most resources and achieving the most savings get commensurate shared savings.

1B. What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area?
If an ACO included all federal beneficiaries and was structured around a geographic area, the quality measurement system would need to be redesigned to reflect the changing program and goals. Firstly, a single parsimonious measure set removing duplication would be needed. This set would need to include measures that adequately cover all of the disparate populations under the new unified program to adequately determine if the health of the broader population was improving. In addition, the types of measures would more logically include truly community-based measures, rather than just ambulatory measures. So, for example, additional public health measures could be included such as the CDC measures of disease incidence and prevalence.

1C. Are there models to consider that better integrate community-based services beyond the traditional medical system?

2. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?

Yes

2A. More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments?

Yes

2B. If so, what would the most critical features of such a "layered" ACO be and why?

We have encouraged CMS to include various service delivery and payment reform initiatives within the ACO program since its inception. While basing ACO payment on the fee-for-service system was necessary at the start of the program we believe it needs to evolve to further overcome the perverse incentives built into the existing system and shift compensation to supporting the Triple Aim™. For example, we think that medical home payments can serve to appropriately compensate primary care physicians for an increasingly prominent role in the continuum of care while still resulting in overall decreases in program expenditures. We also believe that bundled payment can play a critical role within an ACO and in fact a number of our members are in both the Medicare Shared Savings Program and the Bundled Payment for Care Improvement. Including bundled payments can, in particular, help to engage physician specialists who otherwise do not have enough return on investment to participate in ACOs.

E. Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

Conforming other payer contracts away from fee-for-service and toward models similar to the MSSP program is critical to the long-term success of the program. Consistency across contracts will result in faster and bolder results. Two stumbling blocks in this area include an unwillingness of some payers to share data, or only limited data, and the proliferation of quality measures. To the extent that CMS can assist in either of these areas, it would benefit not only Medicare but the healthcare system as a whole. In particular, CMS could develop a competitive program similar to the Comprehensive Primary Care Initiative where providers and payers apply together to enter into a coordinated effort to transform care with the government. However, this should also include grant funds that would be used on a local basis to work out agreements across all of the parties, including Medicare and potentially Medicaid, to implement a singular model of payment and quality measurement.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?
As suggested under E.1., CMS should work to consolidate measures in areas where many payers are willing to come together and agree to common methods. CMS should convene town hall meetings with providers and payers to solicit feedback on its measure set to attempt to evolve it to a core set that could be used across payers.

From: Carlos Martinez [mailto:cmartinez@renalphysiciansofga.com]
Sent: Saturday, March 01, 2014 10:30 AM
To: CMS PioneerACO
Subject: Pioneer ACO. Physician Nephrology led

Dear Sir or Madam:

Please accept this e-mail in response to CMS' Request for Information with respect to new ACO models that encourage greater care integration and financial accountability. We are proposing an innovate physician-driven ACO for nephrologists. Note that I have previously submitted an electronic submission through the CMS Innovation Center's web page. Please accept this e-mail as a supplement to that particular submission.

As you are undoubtedly aware, there have been numerous efforts by other entities/providers to create alternative ACO models for various reasons. Some entities/providers are seeking alternatives for what they perceive as deficiencies in current models. Other entities/providers recognize the efficiencies in current models, but propose alternative innovative models with modifications that will encourage greater care integration and financial accountability through models that don't currently exist. We fall into the latter category. The aim of our proposed model is to put nephrologists at the hub of a redesigned kidney care delivery system that seeks to manage renal and dialysis patients' global health care needs, improve outcomes, and reduce costs. Our innovative ACO model for renal care focuses on the following fundamental guiding principles:

- Physician-driven (as opposed to hospital or dialysis company driven)
- Focus towards nephrology
- Improvement in quality of care and reduction of costs for patient population
- Inclusion of process and outcome measures that will enable a robust evaluation of patient outcomes
- Technology infrastructure that supports clinical coordination, collaboration and continuity of care
- Coordination of care (e.g., predictive modeling, remote monitoring, telehealth, and electronic health information exchanges)
- Evidence-Based Medicine

In a renal care model of an ACO, the nephrologist would be a "principal" care provider coordinating the overall activities. The nephrologists' role in a renal ACO would serve as the accountable "principal" care physician, who is responsible for coordinating care with the primary care physician and other subspecialists, providing preventative care, monitoring care, and overseeing quality measure reporting. Renal care ACOs would have kidney-specific clinical performance measures that could replace some of the typical quality measures that are not necessary for a population with such a high mortality rate. The current renal care delivery systems within the United States provide a perfect opportunity to test a disease-based ACO given the vulnerability of the patients, low incidence rate of kidney disease, sheer size and cost of dialysis and kidney transplant, currently recognized gaps in the fee-for-service and now prospective payment systems, defined nature of renal replacement therapy, and experience with ACO-like programs in CMS demonstrations by the nephrology community. It is my belief that a physician (nephrologist) driven ACO as opposed to a hospital or dialysis company drive ACO is far better equipped to address the effectiveness of incentivizing better care, better health, and lower costs across Medicare Part A, Part B, Part D and the Medicaid programs.

We welcome the opportunity to speak further with someone at CMS regarding this innovative approach to care.

Thanks,

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RFI: Evolution of ACO Initiative at CMS

The Centers for Medicare & Medicaid Services (CMS) are seeking input on the following areas related to the evolution of Accountable Care Organization (ACO) initiatives.
1. A second round of applications for the current Pioneer ACO Model
2. New ACO models that encourage greater care integration and financial accountability

Instructions: The following survey lists the questions found in the Evolution of ACO Initiative RFI which can be accessed through the CMS Innovation Center website at http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/ Please note that you are not required to answer all of the questions in the survey prior to submission, only those that you prefer to answer. Please also note that the text boxes below do not have a character limit.

Submission Date for Comments: To be assured consideration, comments must be received by March 1, 2014.

- Organization Name
  Rural Wisconsin Health Cooperative
- Point of Contact Name Jeremy Levin
- Email jeremylevin@rwhc.com
- Phone Number 608-577-9335
- Please select the option that best describes you.

  Part of a Medicare ACO Part of a Commercial ACO Part of both a Medicare ACO and a Commercial ACO X Not part of a Medicare ACO or a Commercial ACO

- **SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters**

  A. The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes based contracting.

The Model is now entering its third performance year with 23 organizations. In addition to increasingly aggressive risk arrangements, CMS offers eligible Pioneer ACOs the opportunity to transition from fee-for-service (FFS) payments to monthly population-based payments to give these organizations more revenue flexibility in determining how to best motivate providers to improve quality of care and reduce costs for their patient populations. As more and more health care organizations begin to hone their skills in care coordination and engage in outcomes-based contracting, CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

- 1. Would additional health care organizations be interested in applying to the Pioneer ACO Model?

  SKIP Yes No

- 1A. Why or why not?

  This will be uniquely decided by different health care organizations as they look to transfer away from the fee-for-service model to a value-based model.

- 2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?

  Limit the number of selected organizations X Accept all organizations that meet the qualifying criteria

- 2A. What are the advantages and/or disadvantages of either approach?

  As additional applicants apply, CMS should work with organizations to make sure they fully account for the increased risk arrangement of a Pioneer ACO and are financially equipped to handle this profile, as nothing would be worst than a failed Pioneer ACO that then robs beneficiaries of local access. Having more health systems and sections of the country pursuing value-based health care, as Wisconsin has been doing will only strengthen the government payer model.

- 3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to

the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

In rural areas, CMS criteria must recognize the uniqueness of health care in rural communities. Unlike most urban communities, there are not enough providers to support multiple ACOs having exclusive provider networks as the Pioneer ACO model has utilized. Many rural communities are located in areas that could have overlapping ACO presence from multiple urban-based networks. In practice, rural communities need local providers to be able to offer their services to multiple health plans or ACOs. CMS needs to develop criteria that supports a competitive marketplace and allows both affiliated and independent local rural providers to participate in multiple ACOs.

- B. Population-Based Payments: CMS allows Pioneer ACOs to transition to population -based payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

  Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a 40%

reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

- 1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP?

  X Yes No
- 1A. Why or why not?

  Different health systems operate differently and as much flexibility as possible will enhance success.
- 2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?

  X Yes No
- 2A. Why or why not?

  If that will reduce the overall costs to the health care system it should be strongly considered.
- 3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves?

  X Yes No
- 3A. Why or why not?

  CMS should work with organizations to make sure they fully account for the increased risk arrangement of a Pioneer ACO and are financially equipped to handle this profile, as nothing would be worst than a failed Pioneer ACO that then robs beneficiaries of local access. Having more health systems

and sections of the country pursue value-based health care is a positive step that needs to be supported as much as possible.

- 4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

  X Yes No

- 4A. Why or why not?

  CMS should look to alter PBPs to support infrastructure development and chronic disease management, including a Per Member Per Month stipend.

- ## Section II: Evolution of the ACO Model

  The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:
  • Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;
  • Give providers more tools and resources to improve care outcomes and efficiency; and
  • Continue to preserve beneficiary freedom of choice in FFS Medicare.

  CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

- A. Transition to greater insurance risk – ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter

unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues.

- 1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations?

  X Yes No

- 1A. What are the potential benefits and risks to the Medicare program and beneficiaries?

  Standards regarding risk adjustment should create a framework that is consistent nationally but also allows for States' unique circumstances. States vary in their rurality, the organization of providers, type of health plans, as well as the data available for risk adjustment purposes.

- 2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

  Medicare Parts A and B

- 3. Are there services that should be carved out of ACO capitation? Why?

  There may be necessary services, such as home care therapy services, which have very little margin to move away from fee-for-service.

- 4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

The risk adjustment methodology for developing an "adjusted 'cost' basis" agreement needs to take into account the portion of payments made to rural providers in recognition of the additional costs inherent in providing care in rural locations and meeting network adequacy standards. ACOs who are committed to providing local access and who attract more rural enrollees are more likely to see their enrollees using rural providers who face higher stand-by costs and lower economies of scale. This risk is equivalent to other variables traditionally controlled for in a risk adjustment model; methodologies exist and can be adapted to specific circumstances.

- 5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk?

  Enforcement of community access standards for ACOs is absolutely critical to prevent steerage of enrollees and inordinate leverage by health plans against rural safety net providers. To that end, it is important that all ACOs meet strong access standards. As an example, the current Medicare Advantage program statutes and regulations have required CMS to ensure that plan enrollees have reasonable local access to covered services.

  What regulatory and compliance elements in Medicare Advantage would NOT be appropriate for ACOs assuming full insurance risk?

  SKIP
- 6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities?

  Rural status must be considered as a separate risk factor. Risk selection for the ACO or between the ACO and the outside market must be neutralized by actuarially-based risk adjustment methods. Comprehensive risk adjustment that includes the entire market will allow for provider reimbursement from insurers to compensate fairly for differences in patient care needed by different populations as well as the externally driven costs of providing such care in rural localities.

  What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

  SKIP
- Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services.

  7. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

  Failure to risk adjust for socioeconomic status is not an issue unique to Wisconsin or just to rural providers. The National Quality Forum (NQF), one of our countries top arbitrators on diverse quality metrics, is currently initiating a review on this issue: “Under contract with the Department of Health & Human Services, NQF has sought to bring together expert

stakeholders to develop a set of recommendations focused on risk adjustment… The recommendations will specifically address if, when, and how outcome and resource use performance measures should be adjusted for socioeconomic status (SES), race, and ethnicity… As demand for outcome and resource use performance measures continues to grow, the healthcare community is increasingly concerned with the use, effects, and impact of including SES in risk models. There are at least two divergent views on adjusting for these differences, including: 1) adjustment obscures potential problems in equitable care and outcomes, and 2) adjustment is essential for fair comparisons among providers of healthcare services when factors beyond their control influence patient outcomes." Contextual differences between rural and urban practices have long been noted.

- The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking.

8. What are approaches for setting appropriate capitation rates?
Benchmarking should not only measure improvement relative to an ACO's own claims data (as it is under ACA for Medicare), but also improvement relative to national average expenditures. Weighted equally, this will reward those ACOs that lead the nation in delivery of high-quality care, and provide a stronger incentive for those ACOs with higher costs and lower quality to compete for a greater share of savings.

- 8A. What are the advantages and disadvantages of using national expenditure growth trends?

SKIP-sort of answered above

- 8B. What about for using a local reference expenditure growth trend instead?

SKIP-sort of answered above

- 9. What are the advantages or disadvantages of different strategies for risk-adjustment?
(Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)
An ACO's risk adjustment mechanism needs to be designed and approved

to promote local access. The risk adjustment program will act as a fundamental component of successful individual and small group market expansions. Therefore, it is critical that the risk adjustment mechanisms are as accurate and consistent as possible.

- 10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes?
  Reducing co-pays for services delivered by ACO providers is reasonable as long as local access to care is prioritized, as it is absolutely critical to prevent steerage of enrollees and inordinate leverage by ACOs against rural safety net providers.
- 10A. How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?
  SKIP
- 11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?
  Maintaining strong community access standards and preventing steerage of enrollees and inordinate leverage by ACOs against rural safety net providers.
- 12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?
  Traditionally Medicare Advantage plans language protecting beneficiaries from potential marketing abuses limiting beneficiary freedom of choice has been good. RWHC also supports access standards found in Wisconsin Statute 609.22. that requires health plans (with closed provider networks) to respect "...normal practices and standards in the geographic area," and Wisconsin Insurance Code 932 (1) (a) requires covered benefits, with respect to managed care plans, to provide "reasonable promptness with respect to geographic location, hours of operation, waiting times for

appointments in provider offices and after hours care. The hours of operation, waiting times, and availability of after hours care shall reflect the usual practice in the local area. Geographic availability shall reflect the usual medical travel times within the community."

- Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries.

13. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology?

Yes X No

- 13A. What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

  As the approach is to move to a value-based, primary care focused model of care, the attribution should be as local as possible to maintain community access.

- B. Integrating accountability for Medicare Part D Expenditures – An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

- Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes.

1. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?

SKIP

- 1A. What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

  SKIP

- 2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?

SKIP Yes No

- 2A. Why or why not?

SKIP

- 2B. If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

SKIP

- 3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures?

SKIP Yes No

- 3A. What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

SKIP

- C. Integrating accountability for Medicaid Care Outcomes – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.
- CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations.

1. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

X Yes No

- 1A. Why or why not?

As ACOs and health systems are becoming more integrated it makes sense to have ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes, but risk adjustment on the separate populations needs to be made. We believe that there are significant differences in context

between clinics serving small rural communities and those typically serving larger, more affluent communities. Such comparisons will remain misleading until the risk adjustment mechanism can be improved to include differences in socioeconomic status and the unique role and practice patterns of rural primary care providers.

- 2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes?
  (For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?)
  Accountability for all beneficiaries residing in a specified geographic area is reasonable, but a strong tie-in to attribution under the ACO model will be critical.
- 3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?
  We are proud to be part of Wisconsin healthcare that has long promoted and embodied lower-cost and high-quality health care. This is the product of a competitive insurance and provider marketplace with strong access standards. Other states should emulate Wisconsin.
- 3A. What roles should States play in supporting model design and implementation?
  Both in respect to continuing to regulate the private insurance market and maintain strong access standards and oversight of the Medicaid population.
- 3B. Do States have adequate resources to support an ACO initiative in collaboration with CMS?
  Probably not, as enhanced federal funding to support integration of the Medicaid population would better facilitate any transition.
- 4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?

Wisconsin is one of 17 states to have an all payer claims database, the Wisconsin Health Information Organization (WHIO). Transparency of health care information and performance is a winning strategy to engage the general public and encourage their active participation in their health and healthcare. An informed public can improve patient safety, promote efficient healthcare delivery systems, and encourage the creation of reliable quality and efficiency metrics.

- 4A. What are the capabilities of providers in integrating this data with electronic health records?
  Wisconsin has one of the higher adoption rates of electronic health records, especially in rural areas. That said, I would not know about the rest of the country's capabilities.
- 4B. What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?
  RWHC does have concerns that datasets that are currently available may unfairly depict some providers in rural settings as having lower rates for quality and efficiency metrics than their urban counterparts. Claims datasets, which are used to generate both quality and efficiency calculations, do not necessarily contain all payer sources. Addressing concerns that quality reports generated solely from claims cannot accurately portray the clinical care given to a patient-rural or urban-should be handled before broadening the ACO model.
- 5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures?
  (Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?)
  Flexibility and creativity in developing financial arrangements would be most beneficial.
- D. Other Approaches for Increasing Accountability – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.
- A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and

quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns.

1. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?
Community health systems that provide more than 50% of the primary care for a given zip code should be assigned all of the beneficiaries in that zip code.

- 1A. What are the most critical design features of a provider-led community ACO model and why?
The community ACO should agree to act as the Medical Home for its community, coordinate care outside the community and provide comprehensive support for patients with 6 or more chronic diseases. This will provide the highest level of care for the community, lower costs and enhance patient satisfaction. Community ACO's should receive a $10 per member per month payment to finance these additional services.
- 1B. What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area?
Pediatric measures, generic drug utilization and ED utilization measures should be added.
- 1C. Are there models to consider that better integrate community-based services beyond the traditional medical system?

The Patient Centered Medical Home integrates community-based services, but does not pay for them. Community ACO's should be required to share up to 10% of the $10 PMPM payment and shared savings with community resources that agree to provide social support, food, transportation and/or behavioral and mental health services for the most vulnerable patients.

- In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives.

2. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?

X Yes No

- 2A. More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments?

  X Yes No

- 2B. If so, what would the most critical features of such a "layered" ACO be and why?

  Making sure that the attribution of the Medicare patient within a different primary care model is to the rural primary care physician. Currently, a combination of statutory and rule-making issues and rural health care practices are causing only 10-20% of Medicare beneficiaries to be assigned to all-rural ACOs, with the majority of rural beneficiaries being assigned to urban specialists.

- E. Multi-Payer ACOs – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

- 1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

  Rural communities need local providers allowed to offer their services to multiple health plans/ACOs. CMS needs to develop criteria that support competitive marketplaces and allows independent local rural providers to participate in multiple ACOs.

- 2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

  RWHC believes that an intermediate State-level approach should be used to acquire the data necessary for quality measurement. Issuers would submit raw claims data sets to the state government, or state entity responsible for administering the process. Wisconsin is one of 17 states to have an all payer claims database, the Wisconsin Health Information Organization (WHIO). For Wisconsin to not be able to use data already being collected by

WHIO to drive the quality measurement inside of the ACO would be shortsighted.

- Submit

SHARP HealthCare ACO

An Accountable Care Organization

Response to Request for Information (RFI): Evolution of ACO Initiatives at the Centers for Medicare & Medicaid Services (CMS)

March 1, 2014

EXECUTIVE SUMMARY:

Thank you for the opportunity to provide CMS input on policy considerations for the next generation of CMS Accountable Care Organization (ACO) initiatives. Sharp HealthCare ACO (Sharp ACO) is pleased to provide our feedback regarding:

- Approaches for increasing participation in the current Pioneer ACO Model, and
- Suggestions for new ACO models that encourage greater care integration and financial accountability.

Pioneer ACOs have made significant improvements in care processes and the delivery of high-quality care, while reducing utilization of healthcare services for their aligned Medicare beneficiaries. Although most Pioneers have increased quality and achieved the goal of saving money for Medicare, the Pioneer program's financial and quality benchmarking methodology has not appropriately recognized these improvements nor rewarded Pioneers for results. Pioneers have invested significant financial, clinical, operational, and leadership resources to establish the sophisticated care management infrastructures and organizational cultures necessary to support the Triple Aim. They have done so because it is the right thing to do for their patients, and they recognize the current healthcare delivery and financing model is unsustainable. However, Pioneer ACOs need a workable financing and operational structure that adequately incentivizes this important work. Participation in an ACO, including ACO models that encourage greater care integration and financial accountability, would be more attractive to providers if the following areas were improved:

- **Financial Benchmarks** — A regional benchmarking methodology would more appropriately budget and reward providers in varied markets. Additionally, adoption of a more transparent and predictable financial benchmarking model and process would allow ACOs to spread the model to other payers, and it would allow CMS to spread the model to providers across the country;
- **Quality Benchmarks** — Quality metrics should be consistent with those reported under more developed programs such as HEDIS, the Medicare Star Program, and Meaningful Use. Benchmarks should reward organizations that meet the Triple Aim. Noticeable improvements to the quality measurement program will establish CMS as a leader and the ACO quality measurement program as a standard, encouraging broader adoption of ACO measures;
- **Beneficiary Engagement** — Beneficiaries should have incentives to seek care from ACO providers/suppliers through lower cost-sharing and ACO-funded benefit expansion;
- **Beneficiary Attribution —** To reduce turnover in aligned beneficiaries, the methodology for aligning beneficiaries to longitudinal specialists should be amended such that only beneficiaries that have a primary care relationship with an ACO could be aligned to the ACO. Additionally, CMS should implement the "opt in" process for patients attesting that an ACO provider is their primary care physician. Finally, CMS should consider removing opt outs from an ACOs alignment, as care coordination and the identification of high risk patients relies heavily on claims information;
- **Monthly Exclusion Reporting** — It is critical for ACOs to know their number of aligned beneficiaries on a monthly basis, to appropriately measure per beneficiary utilization, quality and financial indicators. Today, beneficiaries who transfer to Medicare Advantage are not included in CMS' exclusion reporting. Additionally, exclusion reporting is currently performed three months in arrears. The complete reporting of exclusions to ACOs needs to be performed on a monthly basis.
- **Expanded Pioneer ACO Data Set** — Inclusion of claims data related to behavioral health services would allow better coordination of care for our highest risk patients; and
- **Criteria for Implementing Preferred Provider Networks** — CMS should provide greater direction as to how care managers in an inpatient setting can provide ACO

beneficiaries preferred provider options while still meeting all requirements under the "choice" regulations.

The balance of this RFI response summarizes the recommendations of Sharp ACO with respect to the current Pioneer ACO model and the evolution of the model to encourage greater care integration and financial accountability. Sharp ACO is a proponent of accountable care and performance-based payments. We look forward to our continued collaboration with CMS and CMMI to attain the Triple Aim for our aligned beneficiaries.

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. Additional Entries Into the Pioneer ACO Program

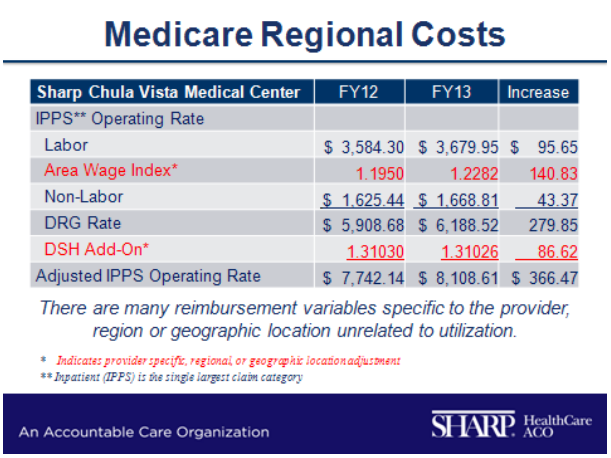
The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes-based contracting. The Model is now entering its third performance year with 23 of the original 32 organizations. CMS is considering giving additional organizations the opportunity to become Pioneer ACOs through a second round Request for Applications process for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?

If organizations had a complete understanding of the financial and quality benchmark methodologies underlying the Pioneer model, we believe additional organizations would ***not*** be interested in applying.

Today, the Pioneer financial benchmark methodology utilizes historical expenditures of aligned populations to project future claims trends using national inflationary factors. Medicare reimbursement varies significantly by provider due to provider-specific, regional and geographic location adjustments; as such, historical claims trends and national inflationary increases do not result in

reasonable Pioneer ACO benchmarks. To illustrate this point, the next page includes a breakdown of inpatient Medicare fee-for-service (FFS) reimbursement components for Sharp Chula Vista Medical Center (SCVMC), one of the providers/suppliers within Sharp ACO, for fiscal year (FY) 2013 compared to FY 2012.

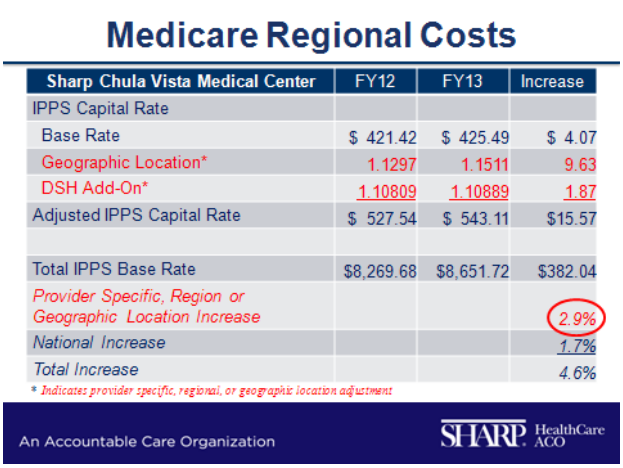


SCVMC's inpatient operating rate increased $366.47 per discharge between FY12 and FY13, of which $227.45 or 62% of said increase is related to provider-specific or regional adjustments. The disproportionate share (DSH) add-on relates to the proportion of Medicaid (Medi-Cal) provided by SCVMC, a factor in the reimbursement formula that cannot be predicted through historical claims or national inflationary factors due to the expansion of Medicaid and the expected reductions in DSH put forth by the Affordable Care Act.

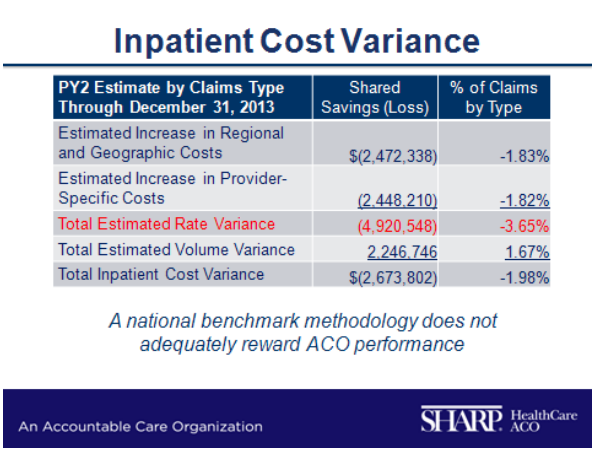
The adjustment to SCVMC's Area Wage Index (AWI) reflects the increase many California hospitals receive to the established "Rural Floor" for hospital labor costs within the state due to the Balanced Budget Act of 1997 (the 1997 Act), which mandates that hospitals in urban areas cannot be paid less than those in rural areas within a given state.

From 2012 to 2014, the AWI for California hospitals subject to the Rural Floor increased a full 5.0%. Because the AWI is budget neutral on a national basis, this increased cost is not reflected in California ACOs' benchmarks. All hospitals in San Diego and Riverside Counties, Sharp ACO's service area, receive this Rural Floor AWI adjustment. This is a significant issue for Sharp ACO, as well as other ACOs in the state, and a major inequity of the Pioneer ACO program because of its

national benchmark methodology. Because the 1997 Act requires Rural Floor payment adjustments be budget neutral at the federal level, all increases for states such as California and Massachusetts, must be offset with reductions elsewhere in the country. Accordingly, ACOs across the nation may be showing shared savings solely due to an AWI decrease for their hospital providers.



Medicare inpatient reimbursement also includes a capital rate component. For SCVMC, the capital rate increased $15.57 per discharge between FY12 and FY13, of which $11.50 or 74% of said increase is due to provider-specific or geographic location adjustments. In total, SCVMC's Medicare reimbursement per discharge increased 4.6% between FY12 and FY13, 2.9% of which was related to a provider-specific, regional, or geographic location increase. Only 1.7% of SCVMC's inpatient reimbursement increase related to a national increase.



Sharp ACO management calculated the impact of this issue across all Sharp ACO discharges in calendar 2013. Although inpatient utilization decreased for Sharp ACO's aligned population in calendar 2013, resulting in a favorable volume variance of $2.2 million, the "Rate Variance" due to provider-specific, regional, and geographic location reimbursement increases for Sharp ACO's providers/suppliers totals an estimated $4.9 million. These inflationary adjustments

are not adequately addressed in the current Pioneer ACO benchmark methodology. Accordingly, Sharp ACO management does not believe a national benchmark methodology based on historical costs of an ACO's aligned population adequately rewards an ACO's performance. This becomes an even greater issue when the Pioneer ACO quality benchmark methodology is factored into the formula.

The Pioneer ACO quality benchmarks were established based on complicated specifications and pre-audited measurement results. Data extraction for use in benchmarking does not appear to be accurate nor consistent across all organizations reporting under the Pioneer ACO measures. During the 2013 audit process, CMS uncovered numerous exceptions to the quality metric specifications, yet those exceptions were not incorporated into the resulting quality benchmarks. Accordingly, the resulting percentile measures vary greatly from those reported under more developed programs, such as HEDIS, the Medicare Star Program, and Meaningful Use. Although the intent of the Pioneer ACO measures was to reward organizations that meet the Triple Aim for Medicare FFS beneficiaries, the published benchmarks make it very difficult for Pioneer ACOs to recoup their investment in the Pioneer program. Consequently, the flawed quality metrics are a deterrent for new organizations to join the Pioneer program.

2. **If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?**

Due to limited resources at CMMI and CMS, and the continued volatility in financial reporting, CMS should limit the number of new additions into the Pioneer model.

Consistent and reliable reporting under the Pioneer model by CMMI and its contractors continues to be a challenge. For example, monthly claims lag and expenditure reports continue to include "exclusions" in the beneficiary count and

claims information, making these reports unreliable. Quarterly exclusion reports do not include those beneficiaries that transferred to Medicare Advantage, making Pioneer ACO data sets and resulting analyses unpredictable. Finally, the baseline benchmark report methodology that drives Pioneer ACO benchmarks does not appropriately reflect the cost of decedents, posing a significant underlying issue for the Pioneer model.

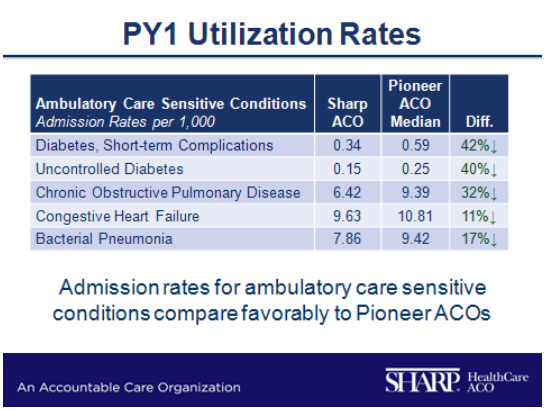
The small size of the Pioneer model has been very beneficial to the learning collaborative, promoting best-practice sharing and transparency. A significantly larger pool of Pioneers would dilute this positive development, and would also weaken relationships with CMMI staff, who are already incredibly stretched.

We recommend the Pioneer program reach a level of consistency and accuracy of reporting prior to broadening the number of participants under the model. To ensure stability and the ability to spread the Pioneer model beyond the pilot phase, transparency, predictability, and accuracy of reporting are needed prior to the expansion of the pilot program.

3. Should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

a. Revise the Financial Benchmark Methodology

The historical benchmark methodology, projected forward using national inflationary rates, does not adequately reward ACO performance. We believe a regional benchmarking methodology would more appropriately budget and reward providers in varied markets. It would also make the Pioneer model more attractive for additional applicants.



Due to its three decades' of managed care experience, Sharp ACO's 2013 utilization rates compared favorably to the 32 Pioneer ACOs in performance year one. However, the Pioneer ACO financial benchmarking methodology did not reward Sharp ACO for this performance. Rather, the Pioneer model favored ACOs with high historical costs, high mortality rates, and/or low reimbursement growth rates due to lower provider-specific, regional, or geographic location increases in relation to national increases. The model provides little financial opportunity for Pioneers who are low cost providers in their market, delivering and coordinating care in a manner that improves health and longevity. To encourage low cost providers to the Pioneer program, and to adequately reward providers that are bending the cost curve, the benchmark must include a regional inflationary factor and it must also take into account market-level utilization.

Additionally, the projection of decedent costs is highly complex and a significant driver of volatility under the Pioneer model. The current proposed revision to the benchmarking model includes an estimate of beneficiaries in their last three years of life. Given the significant cost variation for such beneficiaries, using decedent estimates, historical costs, and national inflationary factors makes the Pioneer financial model highly dependent upon numerous estimates. The growing number of assumptions supporting the Pioneer financial model makes the model highly complex and questionable in its predictability. A more transparent, less complex financial model would reduce risk for Pioneers and attract additional participants. In addition, more of the current Pioneers are likely to stay in the program if CMS can increase transparency and predictability of the model, and clearly

demonstrate how and why individual Pioneers are achieving savings or losses.

Finally, the investments made by Pioneer ACOs in infrastructure costs and personnel must be included in any rebasing for performance years four and five. If these costs are not included, few, if any, current Pioneers will remain in the Pioneer program.

b. Adjust the Quality Benchmarks

The Pioneer ACO quality benchmarks should be designed to reward ACOs who improve the health and care of their aligned beneficiaries, while simultaneously reducing costs. The quality measures should be set in a manner that allows ACOs to recoup their infrastructure and personnel investments. The use of unaudited metrics to establish the percentile rankings has resulted in Pioneer ACO percentile measures that vary greatly from those reported under established programs, such as HEDIS, the Medicare Star Program, and Meaningful Use. For example, for 2013 colorectal cancer screening, the Medicare 4 Stars benchmark is ≥58%, which is only the 50th percentile for ACO metrics. The Medicare 5 Stars benchmark is ≥67%, which equates to the 60th percentile under ACO metrics. To reach the 90th percentile under ACO metrics, 100% colorectal cancer screening compliance is needed. Another example is hypertension control, where Medicare 4 Stars is ≥63%, only the 40th percentile under ACO metrics; Medicare 5 Stars is ≥70%, which would be the 70th percentile under ACO metrics. To reach the 90th percentile under ACO metrics, >79.65% hypertension control is needed.

Although the intent of the Pioneer ACO measures was to reward organizations that meet the Triple Aim for Medicare FFS beneficiaries, the published benchmarks make it very difficult for Pioneer ACOs to recoup their investment in the Pioneer program.

c. Improve Beneficiary Engagement

Success under the Pioneer ACO financial benchmark methodology and quality metrics is highly dependent upon patient engagement. However, responsibility for patient engagement has been placed entirely on the ACOs, while not permitting ACOs to incentivize their patients to seek care from ACO providers/suppliers. To improve patient engagement, aligned beneficiaries should have incentives to seek their care from ACO providers/suppliers through lower cost-sharing and ACO-funded benefit expansion. The ability to offer such incentive programs will allow ACOs to develop innovative strategies, for example wellness programs or rewards, to incentivize beneficiaries to seek care from providers within the ACO, thus maximizing the potential for patients' care coordination and the ability to control quality and costs for those patients. To ensure such programs support the goals of the Pioneer ACO program, any such incentives should be subject to approval by the Secretary prior to being implemented.

Finally, we recommend that aligned Medicare beneficiaries be required to identify a primary care provider for a given performance year. We understand CMS' and Congress' sensitivities to beneficiary freedom of choice; however, requiring providers to be accountable, while ignoring the need for accountability on the beneficiary side, provides significant barriers to meeting the Triple Aim. If a beneficiary selects a primary care physician outside of the ACO, the beneficiary should be removed from an ACO's alignment.

d. Refine the Alignment Methodology

To reduce turnover in aligned beneficiaries, the methodology for aligning beneficiaries to longitudinal specialists should be amended such that only beneficiaries that have a primary care relationship with an ACO could be aligned to the ACO. CMS could allow for a designation of "alignment provider" within the TIN/NPI submission, so that cardiologists and other

internal medicine subspecialists would have patients aligned if they serve as primary care providers as determined by the ACO. This would expand the TIN/NPI provider list and allow for broader application of waivers to increase provider engagement. This would also reduce beneficiary turnover, as patients who are not tightly aligned to an ACO would not be included in alignment.

Additionally, removing skilled nursing facility (SNF) E&M codes from alignment would also increase stability in alignment. Patients in SNFs are generally cared for by physicians during their SNF stay who are not their primary care provider. However, patients are aligned to SNF physicians due to the frequency of visits during their SNF stay, even though these physicians are not providing their primary care post SNF discharge. For the same reason that hospital E&M codes are not included in alignment, SNF E&M codes should be excluded as well, to allow ACOs to include SNF providers who deliver primary care outside of the SNF.

Another refinement to the alignment methodology would be to process geographic utilization of services prior to alignment, rather than as a component of the year-end exclusion process. If a patient historically receives more than a set percentage (e.g., 30%) of their care outside of an ACO's service area, they should not be included in an ACO's alignment. This is particularly important for delivery systems such as Sharp ACO that have "snow bird" populations due to their geographic location.

We also recommend that CMS implement the "opt in" process for patients that attest that an ACO provider is their primary care physician. This "opt in" process into an ACO should also include new beneficiaries aging into the Medicare program. This revision would result in an aligned population that better reflects a delivery system's primary care population. This implementation also favors patient choice and is consistent with the original

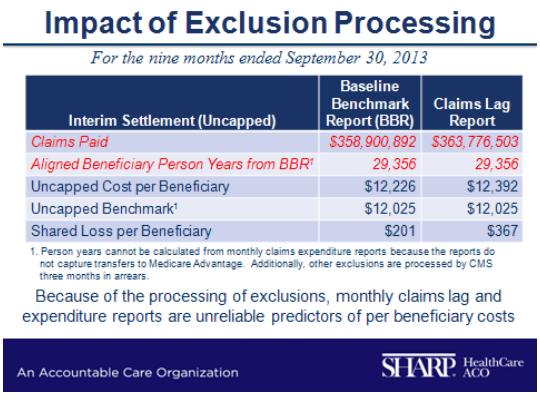
intent of the Pioneer model.

Additionally, we recommend that CMS allow patients who transfer their care to a non-ACO provider during a performance year be de-aligned from an ACO, even if that transfer is within the ACO's service area. This would result in an aligned population that is more reflective of a system's primary care population and would be more consistent with a patient's choice.

Finally, we recommend that CMS consider removing opt outs from an ACOs alignment, as care coordination and the identification of high risk patients relies heavily on claims information.

e. Improve Exclusion Reporting Process

The quarterly processing of exclusions is not adequate to support accurate monthly measurement of an ACO's performance. Today, beneficiaries who transfer to Medicare Advantage are not included in CMS' exclusion reporting. Additionally, exclusion reporting is performed three months in arrears. This results in inaccurate monthly reporting on a per beneficiary basis for every aspect of the program (e.g., quality, utilization, and financial reporting). The following example illustrates this point:



The 2013 third quarter Baseline Benchmark Report for Sharp ACO reported uncapped claims of $359 million. However, the claims lag reports through December 31, 2013 for claims incurred through September 30, 2013, reported paid claims of $364 million, a $5 million variance, which we suspect is due to the inclusion of "exclusions" in the claims lag reports. This

issue is further exasperated due to the inclusion of "exclusions" in the beneficiary count reported in the monthly expenditure reports. As a result of these inaccuracies, an ACO cannot reasonably estimate its monthly shared savings or loss position, a significant limitation of the current exclusion reporting system.

The complete reporting of exclusions to ACOs needs to be performed on a monthly basis. It is critical for an ACO to know the number of aligned beneficiaries on a monthly basis to appropriately measure per beneficiary utilization, quality and financial indicators.

f. Expand Pioneer ACO Data Set

Another barrier to success in meeting the Triple Aim – especially to ACOs that serve a high proportion of patients with behavioral health needs – is the lack of claims data related to behavioral health services. CMS appears to be taking an overly conservative approach to blinding claims related to behavioral health services. Although the original intent was to withhold substance abuse treatment claims for privacy reasons, a much broader set of claims is in fact being withheld.

In comparison with other payors for which we hold outcomes-based contracts, CMS is the only payor that withholds any claims sets. For all other payers where we have outcomes-based contracts, we process all claims and house the full claims set. We recommend that CMS reconsider the behavioral health privacy issue so that the data received by an ACO is commensurate with the risk taken. This would allow better coordination of care for our highest risk patients, as many recent payer analyses show a high correlation between behavioral health diagnoses and high risk factors.

g. Establish Criteria for Implementing Preferred Provider Networks

A final barrier to success in meeting the Triple Aim – especially for ACOs

designed around an integrated delivery system – is the conflict of offering a preferred provider network under the current regulations surrounding patient choice. When an ACO patient discharged from a hospital requires post-acute care, care managers are unable to assist the patient with regard to where that care should be provided. Because there are no criteria that define "choice" (e.g., should five SNFs be offered within a patient's geographic preference, or ten SNFs, or all SNFs), care managers are reluctant to offer any preferred network options even though such options are identified based on superiority in meeting quality, safety, service, care coordination, and aesthetic metrics. CMS should provide greater direction as to how care managers in an inpatient setting may provide ACO beneficiaries preferred provider options while still meeting all requirements under the "choice" regulations. Patients and their families often request help in selecting post-acute care options. Regulations that specify a sufficient number of options that constitutes choice would allow care managers to provide a preferred provider network that better meets a patient's needs and better supports quality and financial outcomes.

B. Population-Based Payments

CMS allows Pioneer ACOs to transition to population-based payments (PBP) that offer revenue flexibility to furnish services not currently paid for under Medicare FFS, and to invest in care coordination infrastructure. Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues. The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries. CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of

the financial settlement of shared savings/shared losses.

1. **Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?**

   A qualifying Pioneer ACO should be able to select varying FFS reduction amounts for Part A and Part B services, as well as for different providers of services within Part A and Part B services. FFS payment reductions may be used to engage providers in meeting the Triple Aim. Preferred facility providers, for example, may be willing to accept a FFS discount if they are able to earn performance-based payments for meeting the Triple Aim. In order to effectively utilize PBPs and performance incentives, flexibility is needed to set the discount not just differently for Part A and Part B, but differently for provider type – even down to the individual provider level. For example, we may utilize different reductions for SNFs than for home health providers, and we would only want to include preferred SNFs and home health providers in the reduction, as opposed to all providers of that type. The ability to set discounts differentially would make the PBP feature more attractive to Pioneers.

2. **Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?**

   CMS should allow ACOs to negotiate discounts with DME suppliers as well as any providers/suppliers that are willing to take a discount off FFS claims. From a regulatory standpoint, any ACOs participating in PBPs and related incentive arrangements must be able to demonstrate their ability to maintain minimum tangible net equity or other reserve requirements that support their ability to meet settlements under their incentive arrangements.

3. **Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to**

receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

CMS should allow ACOs to participate in PBPs regardless of their demonstration of shared savings. Because the current financial benchmarking model does not accurately reflect regional cost variations, Pioneer ACOs may be meeting the Triple Aim even though they are not generating shared savings under the current financial benchmarking methodology. Although our primary recommendation is to revise the financial benchmarking methodology to remove the national inflationary factor and instead account for regional cost structures, we believe open participation in PBPs supports more rapid attainment of the Triple Aim. In the absence of meeting specified levels of savings, CMS could offer an application process for those ACOs that would like to utilize PBPs. Again, from a regulatory standpoint, any ACOs participating in PBPs and related incentive arrangements must be able to demonstrate their ability to maintain minimum tangible net equity or other reserve requirements that support their ability to meet settlements under their incentive arrangements.

4. **Should any additional refinements be made to the current Pioneer ACO PBP policy?**

Given the understanding PBPs are not capitation; no further refinements are required other than those noted in Section I. B. 1, 2, and 3 above.

SECTION II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals: Increase integration of total Medicare and Medicaid expenditures and populations in accountability models; Give providers more tools and resources to improve care outcomes and efficiency; and Continue to preserve beneficiary freedom of choice in FFS Medicare. CMS is seeking input on models that: Transition ACOs to full insurance risk; Hold ACOs accountable for total Medicare expenditures (Parts A, B, and D); Integrate accountability for Medicaid outcomes; and/or Offer ACOs payment arrangements with multiple

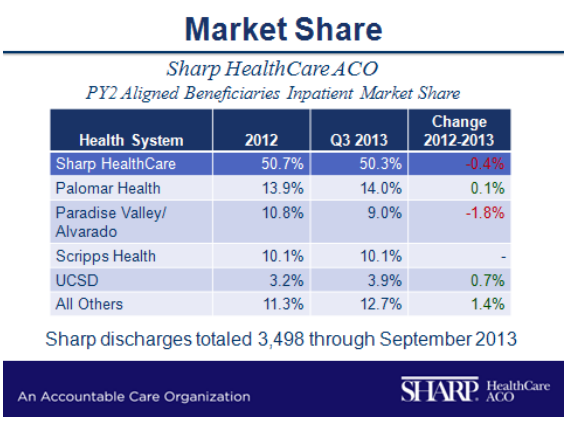
accountability components (such as shared savings/losses, episode-based payments, and/or care management fees).

A. Transition to Greater Insurance Risk

ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time, they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice.

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

Although the members of Sharp ACO have participated in full-risk capitation for over three decades, Sharp ACO does not believe full-risk capitation would be successful under the current Pioneer ACO alignment methodology.



For example, for both 2012 and 2013, only 50% of all inpatient services for aligned beneficiaries were provided by a Sharp ACO inpatient provider/ supplier. Additionally, despite the existence of data use agreements and beneficiaries' choice to share data, several major inpatient providers/ suppliers in Sharp ACO's market refuse to share data with Sharp ACO for Sharp ACO patients under their care. The FFS environment is a disincentive for non-ACO providers/suppliers to share patient data, even though the sharing of such data is in the best interest for patients' care coordination, both pre- and post-discharge.

Another issue that deters the success of full-risk capitation is the significant turnover of ACO beneficiaries from year-to-year. In researching our data, we found that beneficiaries accessing longitudinal specialists tended to align and dis-align

with Sharp ACO due to choosing non-Sharp ACO providers for their specialty services. Without strong, consistent alignment, full-risk capitation imposes too much financial risk on ACOs with no ability to authorize services or adjudicate claims.

2. **What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)**

ACOs that are willing to accept full-risk capitation should have the option to be responsible for all parts of care. Much of the savings under full-risk capitation comes from substituting high cost Part A services with lower cost Part B or Part D services. Additionally, full-risk capitation allows organizations to provide the most cost-effective and consumer-friendly care in settings that do not currently qualify for Medicare reimbursement, such as outpatient palliative care (i.e., pre-hospice services), home care for non-homebound patients, telemedicine, and nurse call centers. Finally, ACOs in states that are not participating in duals demonstration projects may want to be accountable for Medicaid payments/claims. Because full-risk capitation brings predictability of payments to CMS, all categories of spending should be considered by CMS. From a regulatory standpoint, any ACOs participating in full-risk capitation must be able to demonstrate their ability to maintain minimum tangible net equity or other reserve requirements that support their ability to pay incurred but not reported claims and any settlements accrued under incentive arrangements.

3. **Are there services that should be carved out of ACO capitation? Why?**

If an ACO accepts capitation for a defined set of services, there should not be any carve outs for defined services. However, to ensure success within a capitation environment, the alignment methodology would need to exclude any patients that receive more than a set percentage of their care outside of an ACO's service area and patients who transfer their care to a non-ACO provider during the year (e.g.,

aligned beneficiaries who follow a PCP who moved to another medical group).

4. **What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?**

The ACO would want the ability to negotiate agreements with individual providers for which the ACO maintains the risk (e.g., hospitals, SNFs, home health organizations, etc.). The ACO would be required to negotiate and administer the agreements and process claims. In the absence of agreements, the ACO would be required to pay claims based on Medicare FFS rates.

5. **What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would not be appropriate for ACOs assuming full insurance risk?**

From a regulatory standpoint, any ACOs participating in full-risk capitation must be able to demonstrate their ability to process claims within established regulatory time frames and maintain minimum tangible net equity or other reserve requirements that support their ability to pay incurred but not reported claims and any settlements accrued under incentive arrangements. Given patient choice, ACOs may not be able to authorize services or deny claims based on the existence of sufficient "in network" providers/suppliers. This issue is a significant deterrent to full-risk capitation in a FFS environment.

6. **What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?**

As noted above, any ACOs participating in full-risk capitation must be able to demonstrate their ability to process claims within established regulatory time frames and maintain minimum tangible net equity or other reserve requirements that support their ability to pay incurred but not reported claims and any settlements

accrued under incentive arrangements. In the State of California, the Department of Managed Health Care (DMHC) regulates any organizations accepting full-risk capitation by requiring such organizations carry specific licenses, undergo periodic audits and fulfill other regulatory requirements. Finally, in a capitated environment where ACOs may be able to negotiate rates for aligned beneficiaries that are reduced from current Medicare fee-for-service rates (e.g., to establish funds available for incentive arrangements), a waiver may be needed such that a contracted provider/supplier be excluded from providing the reduced rate to their entire Medicare fee-for-service population.

7. **Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?**

   Depending on the structure of the full-risk capitation model, ACOs may need infrastructure to support claims payment, marketing, enrollment, and member services, in addition to their ongoing investment in care management programs. ACOs that do not have this infrastructure today may contract with a health plan or third party administrator to acquire these health plan functions. As noted above, in the State of California, the DMHC requires any organizations accepting full-risk capitation to do so under a licensed health plan.

8. **What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?**

   Under either a capitation model or shared savings model, the use of a national trend to set the capitation rate or benchmark, respectively, creates advantaged and disadvantaged ACOs and does not appropriately reward ACOs for their performance. Although under a shared savings model the disadvantage sits solely

with the ACO, under a capitation model the disadvantage sits with CMS. The use of a national benchmark will encourage only advantaged ACOs to accept full-risk capitation, which will in turn reduce the savings opportunity currently held by CMS.

9. **What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)**

Health status or Hierarchical Condition Category (HCC) model risk adjustment is a key component of all of Sharp HealthCare's full-risk capitation payment arrangements. While it is an imperfect model, health risk adjustment has the benefits of being a standard practice and a known and acceptable approach. Where an ACO is looking to take on significant risk, using a consistent approach reduces the risk of unknowns. Health status adjustment also allows for comparison across ACOs, independent of local or regional cost variances.

10. **What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?**

Whether full-risk or shared savings, we strongly recommend rewarding beneficiaries for more actively participating in the ACO model. Encouraging in-network care, as defined by the individual ACO, through eliminating or lowering copays or other benefit design changes will decrease the costs of uncoordinated, out-of-network care, and deliver in-network care which is likely to be safer, and more connected to all the other high-value services the ACO provides (e.g., post-acute care, care coordination, disease management, end-of-life care, etc.). We also recommend that CMS reward beneficiaries, through cost-sharing reductions, for selecting an ACO-aligned primary care physician – because of the benefits of care coordination and also so that over time, alignment reflects a patient's actual choice. Other opportunities for reducing or eliminating beneficiary cost sharing are no

copay for vaccinations or for procedures or services that manage chronic disease.

Lastly, we recommend that ACOs have the option of developing a "branded" Medicare supplement/Medigap plan and/or Part D benefit, offering benefit designs that would not only ensure good stewardship of the Medicare dollar, but also provide opportunities for patient engagement in the ACO by encouraging, for example, use of an ACO's providers. We believe an ACO-branded Medicare supplement (Medigap) plan could help us meet the Triple Aim, and recommend that CMMI actively support such a benefit in the evolution of ACOs. Access to an ACO Medigap plan would give patients a tangible benefit to being part of the ACO. Offering a Medigap plan would also be helpful in markets with high Medicare Advantage penetration, where patients enjoy the ease of getting all their Medicare benefits in a coordinated fashion.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

The ability to meet the infrastructure requirements of Medicare Advantage should be required for ACOs assuming full-risk capitation. We believe the risk under full-risk capitation is significantly higher than the risk assumed by Medicare Advantage providers due to the continuation of choice under the ACO full-risk model. Accordingly, CMS should ensure, at a minimum, that ACOs interested in full-risk capitation meet all applicable requirements of Medicare Advantage.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

CMS could limit the number of marketing materials provided ACO beneficiaries and retain full approval rights, just as it does under the shared savings program

today. Additionally, CMS could provide the same capped methodology used under the shared savings model today to reduce risk to ACOs under full-risk capitation.

13. **If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?**

We recommend that CMS adopt strategies that encourage beneficiaries to "choose" the ACO model, choose their ACO, and select a primary care provider within the ACO. This approach is more forward looking (i.e., where I want to get my care today and going forward), than backward looking (i.e., where I got my care for the last three years). We recommend CMS allow patients to "opt in" to the ACO so that the aligned population better reflects the ACO's primary care population – and would favor a patient's choice over a math formula. We also recommend that CMS allow patients who transfer their care during the year (e.g., follow a primary care physician who moved to another medical group) to be de-aligned, or removed from the risk pool, even if that transfer is within the service area. Again, this would result in an aligned population that is more reflective of the system's true primary care population, while simultaneously reflecting patient choice.

B. Integrating Accountability for Medicare Part D Expenditures

An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.

1. **Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business**

arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

Because of the large number of Part D providers providing benefits for our aligned beneficiaries, each with only a small percentage of our aligned beneficiaries under their plan (i.e., none with more than 10%), it did not make sense for us to pursue a business relationship with any one Part D plan. Additionally, as we assessed those beneficiaries that held Part D plans, many were duals who will be leaving our Pioneer ACO in 2014 under the California duals demonstration project. Accordingly, aligning with Part D providers resulted in significant work for our ACO with very small reward, due to the small number of co-aligned beneficiaries with each Pharmacy Benefit Manager (PBM). We did have exploratory conversations with two Part D providers, which led to our assessment and conclusions noted above.

CMS could allow ACOs the option of developing a "branded" private Part D plan, and offer benefit designs that would not only insure good stewardship of the Part D dollars, but also provide opportunities for patient engagement in the ACO by encouraging, for example, coverage of key over-the-counter medication (e.g., aspirin) and lower co-payments for key chronic medications and/or when using an ACO's owned pharmacy.

2. **Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?**

We are not interested in accepting insurance risk as a Part D sponsor, unless ACOs are allowed to provide a single, stand-alone Part D benefit to their aligned beneficiaries as either a private label product through a single PBM or as a separate

Part D sponsor. Working with multiple Part D sponsors without a unified benefit, formulary and rule-set across the beneficiary population is administratively too difficult to manage appropriate utilization and costs, creating an environment where taking risk would not be of interest.

3. **Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?**

Until ACOs are allowed to provide a single, stand-alone Part D benefit to their aligned beneficiaries as either a private label product through a single PBM or as a separate Part D sponsor, we do not believe ACOs will be interested in assuming Part D risk.

C. Integrating Accountability for Medicaid Care Outcomes

As part of the State Innovations Model, CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders.

1. **CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?**

ACOs that have dual-eligible patients in their aligned population – particularly those who do not have managed care options for duals in their state – should have the option of taking full accountability for Medicaid costs and outcomes. This would provide incentives to build more coordination of care for Medicaid benefits (e.g., social and home supports) within the ACO, better serving these vulnerable patients. This should be an option, not a requirement, as many ACOs do not have the experience or expertise of being accountable for the full Medicaid benefit. Additionally, many states such as California, are already participating in the duals demonstration project.

2. **What populations should CMS prioritize in integrating accountability for**

Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

ACOs should be able to choose the subset of dual-eligibles for which they will take accountability. For example, ACOs that have developed a strong geriatric model of care may not have the right model of care for younger, disabled patients. ACOs should not be required to take accountability for patients who have not been cared for by the ACO, unless the patient is opting into the ACO and choosing an ACO primary care physician.

3. **What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?**

States should decide their role through their participation, or lack thereof, in the duals demonstration project.

4. **What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records (EHR)? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?**

ACO capabilities for managing the dual population vary from ACO to ACO. At Sharp ACO, we have not attempted to combine Medicare and Medi-Cal FFS data to drive care improvement efforts. However, for patients seen at Sharp ACO's

providers/suppliers, clinical information is managed through a common EHR platform across the provider network, so clinical information for the dual population does drive care management efforts for identified high risk patients.

5. **What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?**

   For ACOs interested in managing the dual population in states that are not participating in the duals demonstration project, we would recommend that CMS work directly with the states to offer a unified shared savings arrangement that combines Medicare and Medicaid expenditures for an ACO's aligned population.

D. Other Approaches for Increasing Accountability

CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

1. **A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?**

   Given that California is participating in the duals demonstration project, a provider-led community ACO is not an option for us or our market.

2. **In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?**

We would be interested in evaluating any service delivery initiatives that may be available to Sharp ACO for our aligned population. The comprehensive primary care model may be of interest to Sharp ACO, as we have a strong primary care provider base within our provider/supplier network. Given the lack of predictability and complexity of the Pioneer ACO financial benchmarking model, we are not interested in overlaying another payment reform model to the Pioneer ACO program. Accordingly, we are less interested in combining payment reform models with the evolution of the Pioneer ACO model.

E. Multi-Payer ACOs

CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.

1. **How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?**

If CMS adopts a more transparent and predictable financial benchmarking model and process, ACOs may be more comfortable spreading such a model with other payers, and those payers will be able to replicate the model and analyze the Medicare experience. This would speed adoption in the private market, as would refinements to the attribution model to make it one that other payers could easily

support and adopt.

2. **How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?**
CMS is a standard bearer and pace setter. To that end, this positional leverage is most effective if CMS can promote stability and continuous improvement in the quality reporting program, increasing its institutional capacity for establishing:

   a. **Agreement around metrics that are seen widely to be clinically relevant.** An example is hemoglobin A1c control in diabetics is measured in two ways in the ACO measure set, and hemoglobin A1c < 8 is not recommended by the American Diabetes Association Geriatric Committee due to being too clinically tight a control for frail elders. The choice of this measure seems both redundant and clinically unwise.

   b. **Metrics that are standard measures with broad use.** An example is using the more common HEDIS specification for Medication Reconciliation rather than the unusual ACO Medication Reconciliation measure, which has been a source of misinterpretation, reinterpretation and reporting error. Another example is the ACO metric for tobacco use, which is different from the Meaningful Use metric, yet both metrics cover the same population of patients.

If CMS can make noticeable improvements to the quality measurement program, this will establish CMS as a leader and the ACO quality measurement program as a standard, encouraging broader adoption of the ACO measures.

RFI: Evolution of ACO Initiative at CMS

The Centers for Medicare & Medicaid Services (CMS) are seeking input on the following areas related to the evolution of Accountable Care Organization (ACO) initiatives.
1. A second round of applications for the current Pioneer ACO Model
2. New ACO models that encourage greater care integration and financial accountability

Instructions: The following survey lists the questions found in the Evolution of ACO Initiative RFI which can be accessed through the CMS Innovation Center website at http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/ Please note that you are not required to answer all of the questions in the survey prior to submission, only those that you prefer to answer. Please also note that the text boxes below do not have a character limit.

Submission Date for Comments: To be assured consideration, comments must be received by March 1, 2014.

- Organization Name St. Vincent's Health Partners, Inc.
- Point of Contact Name First Last Thomas Raskauskas
- Email Thomas.raskauskas@stvincentshealthpartners.org
- Phone Number 203-275-0202
- Please select the option that best describes you. Part of both a Medicare ACO and a Commercial ACO

- **SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters**

A. The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes based contracting. The Model is now entering its third performance year with 23 organizations. In addition to increasingly aggressive risk arrangements, CMS offers eligible Pioneer ACOs the opportunity to transition from fee-for-service (FFS)

payments to monthly population-based payments to give these organizations more revenue flexibility in determining how to best motivate providers to improve quality of care and reduce costs for their patient populations. As more and more health care organizations begin to hone their skills in care coordination and engage in outcomes-based contracting, CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

- 1. Would additional health care organizations be interested in applying to the Pioneer ACO Model?
  No
- 1A. Why or why not? Pioneer ACOs are being asked to accept more insurance risk, rather than concentrate on medical management and medical services. In order to be able to accept insurance risk, the organization needs to be able to: receive real time, accurate claims data; provide prospective utilization review; receive real time, accurate enrollment information; encourage a mechanism for prospective enrollment attribution (selection of PCP); or have attribution at a network wide level of care (geographic assignment for example) rather than retrospectively through the current methodology which can assign attribution to specialists rather than true PCPs. It is financially unsound for an ACO to accept retrospectively assigned attribution after the costs have been incurred to the network, yet not attributed by CMS. Insurers have the capabilities to provide insurance risk because they have the ability to know who their beneficiaries are and can prospectively plan for expenditures for services. ACOs do not receive this data until expenditures have occurred, and therefore are at different financial risk than insurers. Additionally, insurers receive the funds upfront, whereas ACOs receive funds far after expenditures have occurred. This requires ACOs to seek alternate financing, and to develop a business model without the ability to accurately project revenues. Providers are better equipped than insurers to control quality and utilization of services risks through care coordination at all transitions of care and population health management, and reimbursement models are currently being developed to fund these activities. If funding streams to ACOs can be frontloaded, and

better ability to define the pool of beneficiaries, ACOs can move toward greater risk acceptance.

- 2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?
  Limit the number of selected organizations
- 2A. What are the advantages and/or disadvantages of either approach?
  For an ACO, the ability to demonstrate transformation of care should be a requirement, either at the start, or within the first three years of an ACO contract. This includes certification/recognition of at least a majority of the primary care providers as PCMH, and the ability to demonstrate accreditation by NCQA or URAC that the critical elements of clinical integration at the ACO level are in place. Capabilities of network capture of clinical data across systems of care should be a requirement. Additionally, there is a need to demonstrate the ability to have accountability for the total cost of care across the network, including ambulatory, inpatient, SNF, rehab, HHC etc. through care coordination. An ACO needs to demonstrate that it has the capability to connect all providers of care electronically for sharing of data, and have the analytic capabilities to accept and understand the data so that population management can occur.
  3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model? Because of the initial un-reimbursable investments required by an ACO to develop the necessary capabilities to provide care coordination and accept risk, we recommend the advanced payment model should be reconsidered.

- B. Population-Based Payments: CMS allows Pioneer ACOs to transition to population -based payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently

requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a 40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

- 1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP?
  Yes
- 1A. Why or why not?
  Consideration of FFS based upon quality metrics should be considered. Differential payments to providers based upon ability to improve quality metrics and utilization could result in a tiered FFS model.
- 2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?

No comment

- 2A. Why or why not?
  no comment
- 3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves?
  No
- 3A. Why or why not?
  When developing an ACO, the investments first concentrate on infrastructure, followed by process, then outcome. Consideration of a several year reimbursement model based heavily on investment of infrastructure and less on outcomes, with a reversal after 3 years to invest more on outcomes and less on infrastructure. Our suggested reimbursement model is below in the grid:

Metric	Year 1	Year 2	Year 3
Infrastructure investment	60%	30%	10%
Process reimbursement	30%	50%	40%
Outcome reimbursement	10%	20%	50%

- 4. Should any additional refinements be made to the current Pioneer ACO PBP policy?
  Yes
- 4A. Why or why not?
  no comment

- ## Section II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with

three major goals:

• Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;

• Give providers more tools and resources to improve care outcomes and efficiency; and

• Continue to preserve beneficiary freedom of choice in FFS Medicare.

CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

- A. Transition to greater insurance risk – ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues.
- 1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations?
  No
- 1A. What are the potential benefits and risks to the Medicare program and beneficiaries? In consideration of the ACO model, there needs to be a clear delineation of insurance risk versus medical care delivery and medical management risk. Payments to ACOs providing insurance functionality can result in duplication in services and redundancies in organizational structure, adding to overall cost. ACOs do not pay FFS claims, and therefore they do not receive the same claims information as Medicare Advantage plans, and would therefore be at a great financial disadvantage. Additionally,

as MA pays the claims, the data received is timelier than provided to ACOs by CMS. CMS should consider clearly delineating the insurance functions that the Medicare Advantage plans would be paid to provide, and then consider redesign of the reimbursement model for both medical services and medical management that can be provide by ACOs. These can be transitioned over time to ACOs, but most importantly the prospective assignment of beneficiaries to ACOs is needed. As stated earlier, MA plans know whom they are financially responsible for prospectively, and receive funding regularly. The disadvantage to ACOs is no clear assignment of beneficiaries in the current model until year end, and an additional 6 month delay in the shared savings funding. Examples of insurance functions would be receiving and paying claims, prospective utilization review, enrollment/disenrollment and call center. Medical services and medical management would include the usual FFS billable services from various provider types (doctors, dentists, hospitals, urgent care, SNFs, etc.), as well as contracted medical therapy management. This would include care coordination across the continuum of care, medication therapy management, and other services delineated later in this application. There should be a clear contractual expectation, along with the capability of the organization to demonstrate these capabilities.

- 2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries) We think that risk should be limited to medical services and medical management, including MTM at the ACO level. This would entail carving out the MTM responsibilities out of the PDP and redistributing the MTM associated funds to the ACO. The MLR of 85% should be given to the ACO, and the administrative insurer functions remain with Medicare, until the ACO demonstrates the capabilities of insurance functions.

- 3. Are there services that should be carved out of ACO capitation? Why?
- The functions of the insurer roles should be carved out. This includes receiving and paying claims, prospective utilization review, enrollment/disenrollment and member call center. Provider network responsibilities would initially be reimbursed for medical services and

medication therapy management would fall under the ACO. The ACO would need to demonstrate the capabilities of insurance functions, and then redistributing the funds to the ACO as insurer functions are demonstrated.

- 4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?
  This would need to be part of the insurer responsibilities, and the ACO would need to demonstrate these capabilities prior to receiving funds for these duties.

- 5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? This could vary by state, and state insurance regulators would need to be involved in this discussion. The requirements for capital reserves, utilization review and denial of care would need to be clearly delineated for the ACO, as well as potential accreditation for such duties. Expectations of network adequacy for the defined ACO would need to be validated. ACOs should be accredited by a nationally recognized organization such as NCQA or URAC validating the capabilities.

  What regulatory and compliance elements in Medicare Advantage would NOT be appropriate for ACOs assuming full insurance risk?
  no comment

- 6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? State licensure requirements vary by each state's laws. ACOs would need to develop legal expertise and infrastructure in areas outside their traditional knowledge base, i.e. providing medical services and medical management. The ability to provide actuarially sound reimbursements as well as the ability to challenge the actuarial data from CMS for the population under consideration would also be necessary to accept this risk. The ability to achieve the necessary reserves is a current struggle, as potential investors or reinsurance options would have to be explored.
  What types of waivers to current regulations and/or fraud and abuse laws, if

any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?
The ACO needs to demonstrate the capabilities of an integrated network to meet the FTC anti-trust guidelines. Waivers for the requirement of 3 day admission prior to the use of a SNF, telehealth waivers Section 1834(m) of the Act allows Medicare payment for telehealth services where the originating site is one of eight healthcare settings that is located in a geographic area that satisfies certain requirements. CMS waives the geographic area requirement for telehealth services furnished to eligible beneficiaries during an innovative reimbursement model episode, as long as the services are furnished in accordance with all other Medicare coverage and payment criteria; waiver for the direct supervision requirements 42 C.F.R. § 410.26(b)(5) for "incident to" services, provided that such services are furnished as follows:
The services are furnished to a beneficiary who does not qualify for Medicare coverage of home health services under 42 C.F.R. § 409.42, and the services are furnished in the beneficiary's home after the beneficiary has been discharged from an Episode Initiator;
The services are furnished by licensed clinical staff under the general supervision of a physician or other practitioner as defined in 42 C.F.R. § 410.32(b)(3)(i);
The services are furnished by licensed clinical staff and billed by the physician or other practitioner using a Healthcare Common Procedures Coding System (HCPCS) G-code specified by CMS;
The services are furnished not more than once in a 30-day episode, not more than twice in a 60-day episode, and not more than three times in a 90-day episode; and
The services are furnished in accordance with all other Medicare coverage and payment criteria, including the remaining provisions of 42 C.F.R. § 410.26(b).

Waivers for fraud and abuse including specified gainsharing, incentive payment, and patient engagement incentive arrangements in connection with this innovation design.

- Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services.

7. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk? Insurer functions would need to be developed including: a call center for member services; ability to provide prospective utilization management; ability to receive and pay claims; ability to establish an adequate provider network; ability to enroll/disenroll members and provide insurance cards; ability to advertise; and the ability to calculate and ensure actuarial sound reimbursement models;ability to demonstrate cash

reserves; demonstrate adequate stop-loss and/or reinsurance would be necessary.

- The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking.

8. What are approaches for setting appropriate capitation rates?
no comment

- 8A. What are the advantages and disadvantages of using national expenditure growth trends? No comment
  8B. What about for using a local reference expenditure growth trend instead?
  no comment

9. What are the advantages or disadvantages of different strategies for risk-adjustment? Without risk adjustment, ACOs have an incentive to enroll healthier members and avoid sick members, especially when they cannot vary premiums by health status or other known factors likely to affect health care costs. Risk adjustment helps ensure that payments to ACOs reflect the differences between their enrollees and the eligible population. Strong risk-adjustment models reduce competition among plans for favorable risks, help mitigate adverse selection, provide incentives to enroll high-cost individuals, and help ensure that plans that enroll high-cost patients have the resources needed to provide efficient and effective treatment. Prospective models under-predict costs of high cost members and can over predict costs of low cost members. Allowing an ACO to more properly code the risk of its members, and making the adjustment based on prior risk score will need to be examined to prevent abuse of the risk adjustment. ICD-10 hopefully will provide more accurate reflection of the diagnoses of members. Lengthening the risk adjustment period to a three year historical basis should be considered. As an established patient is one that has been seen within the past three years, there is precedent for using this as a basis of risk adjustment. Adding a Health Risk Assessment would be of benefit as well. Consideration of using value based designs for member engagement and compliance should also be considered.
We propose allowing the ACO to provide a risk adjustment methodology including number of chronic diseases, number of different classes of chronic medications, ER/urgent care utilization and hospitalization, number of unique specialists in care, ratio of PCP to ED visits, cost expenditures for medications, and high cost low utilized drugs requiring frequent provider visits.
Geographic risk adjustment should be a consideration as we are in Connecticut, the 9th highest Medicare cost per beneficiary in 2009 (Kaiser Family Foundation) in the country. In particular, Fairfield County is the highest within the state of Conencticut.

- (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

- 10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? Using the model of value based insurance design, incentivizing members for making an annual visit with the PCP, as well as planned chronic disease management for certain disease states such as diabetes and CHF to provide the opportunity to capture the necessary biometrics needed to care for chronic conditions. Incentivizing the beneficiary to complete an HRA and welcome to Medicare health visit would provide the PCP with valuable information not readily captured in traditional office visits. Lowering or waving co-pays for chronic medications, and incentivizing generic medication usage would be of benefit. Providing incentive to use the ACO network, with increased out of pocket costs allows for out of network would result in better medical management and data sharing. A suggestion for an ACO using this model would be to partner with the University of Michigan Center for Value Based insurance design to monitor the program's effectiveness.
- 10A. How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid? There would be a need to consider differential out of pocket costs due to receiving care within or outside of the ACO network. Differential co-pays can be used, as well as considering lower part D premiums for member compliance with generic utilization and medication adherence. These enhancements would have to be carefully crafted, and we suggest working with the University of Michigan Center for Value Based insurance design. Currently in Connecticut, the State Employee program has used this enhancement model, and demonstrated the following:

  The Incentives

  HEP enrollees pay less for health care than those who do not elect to participate. Specifically, HEP offers enrollees:

Exemption from an insurance premium surcharge imposed on non-enrollees (savings of $100/month);
Exemption from the deductible (potential annual savings of up to $1,400/family);
Reduction or elimination of copayments for chronic disease management medications;
Elimination of copayments for office visits for chronic conditions; and
Incentive payments of $100 annually if a member, or member's dependent, with a targeted chronic condition complies with all HEP requirements in the year.

The Results

Participants Respond to Incentives and Accept Accountability. About 98 percent of the approximately 54,000 eligible Connecticut state employees and retirees have enrolled in HEP. These individuals have overwhelmingly complied with HEP requirements: after 15 months of follow-up, Connecticut estimates that 99 percent have met expectations.

Clinically Nuanced Incentives Increase Evidenced-Based Care and May Promote Favorable Changes in Utilization. According to the Connecticut State Comptroller, monthly primary care visits have increased, while emergency department and specialist visits have decreased. (See figures.) Adherence to heart disease, blood pressure, cholesterol, and diabetes medication has modestly improved since HEP's launch.

Increases in Health Care Spending May Be Slowing. The medical-spending trend for HEP enrollees decreased from +13 percent in fiscal year 2011 to +3.8 percent in fiscal year 2012. A formal evaluation funded by the Robert Wood Johnson Foundation is now underway and will provide more conclusive information on HEP's impact on spending.

- 11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards? Large losses resulting in potential reduction in staff can occur. A safeguard would be a requirement for capital reserves, stop loss and/or reinsurance, and requirement to report staffing on an annual basis could mitigate this.
- 12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

Seeking approval in a timely fashion from CMS or CMS delegated entity for all marketing materials, requiring non-English translations by certified medical translators, and capping dollars per beneficiary on marketing spend are potential safeguards.

- Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries.

13. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? Yes

- 13A. What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution? Prospective alignment allows more proper utilization of resources for an ACO, and establishes up front its membership. This allows for more planning of budget and allocation of resources.
- B. Integrating accountability for Medicare Part D Expenditures – An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation.
- Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes.

1. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?

1. While collaborations between ACOs & PDPs with a goal of enhancing health outcomes for their mutual enrollees is a positive initiative in theory effectiveness of these collaborations face challenges.

a. The sheer number of PDPs and Part D options that are available to enrollees. - For example in Connecticut there are 14 sponsors and 28 individual options for enrollees. These plans have varied formularies and each option has a unique monthly premium along with tiered copays. These factors may impede the patient from obtaining the most appropriate drug prescribed. It may not be in the formulary; or it may cost the patient more because it is not the preferred drug.

b. Preferred Pharmacy Networks- Preferred pharmacy networks in Part D plans are limited access networks where certain pharmacies have a contractual arrangement with a PDP to accept their enrollees and dispense medication to these enrollees at a deeply discounted rate. Limited networks may be a barrier for ACOs enrollees who don't live in close proximity to the pharmacy. This may have a detrimental impact on their ability to obtain their medications and refill prescription

c. Data share- Will the PDP have the ability and be willing to share prescription drug claim data with the ACO This helps to maintain a current updated drug list.

- 1A. What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

  While there are many challenges for an ACO to collaborate effectively with a Medicare Part D plan regarding the distribution and administration of prescription drugs, there is potentially an opportunity to develop a business agreement with the Part D plans to administer the Medication Therapy Management portion for the ACO's covered lives that the PDPs are responsible for utilizing pharmacists employed by or contracted through the ACO. This innovative proposal keeps the medication management piece within the medical component of care and provides the appropriate time and place for this care management component to occur.

  1a. Provide standard contractual language for ACOs wishing to partner with PDPs. Contract language that covers data sharing, that allows patients of the ACO to switch PDPs if it is determined by the ACO that a more appropriate plan is available to the patient based on a review of the plans and the patient's medical records, that directs the redistribution of PDP MTM funds to the ACO for integrated MTM & Coordination services.

- 2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?
  No
- 2A. Why or why not?
  The focus of the ACOs is to coordinate care. To dedicate time and effort in administering a prescription drug program is not necessarily an effective use of time. ACOs can still impact cost through best practices and influencing prescribing habits. ACOs do not want to assume financial risk for pharmaceuticals.
- 2B. If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method? No comment
- 3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? NO
  No
- 3A. What other mechanisms would allow ACOs to assume accountability for Part D outcomes?
  Sharing of pharmacy data or becoming a Part D Plan sponsor.
- C. Integrating accountability for Medicaid Care Outcomes – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes.
- CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations.

  1. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?
  No
- 1A. Why or why not?
  Medicare and Medicaid have different funding sources, oversight reimbursements, reporting mechanisms, infrastructure and patient

demographics. A supermajority of those aged 65 and older have Medicare, making it in essence the sole provider of elderly care. Medicare is governed through CMS in Washington. Medicaid responsibility is shared between CMS and the states, with each state having a CMS approved Medicaid plan which describes the state services which fit in the federal framework, overarching principles and parameters. Excluding dual eligible enrollees, Not all medical practices are equipped to provide care to these populations. Many offices can treat children or pregnant women, not the elderly, and vice versa. As they are completely different product lines, providers should be able to select either or both, and not be required to accept both.

- 2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? Populations to consider for prioritization depend upon the makeup of the ACO and the ability to provide care to children, adults and /or the elderly. For those who can only provide care to mainly children, special populations would include pregnancy, children with special needs, CHIP and dual eligibles under 21 years of age. For those who can provide care to adults, the priorities for integrating accountability could include long term care, dual eligibles between ages 21-65, and pregnancy. Populations in certain geographic areas is a convenient administrative method to attribute beneficiaries to ACOs.

  (For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?)
- 3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?

  States play an integral role in the financing, service array, service delivery systems and a host of other major components of the Medicaid system. While on average states cover 43% of the funding of Medicaid, the state financing portion ranges from a low of 25% to a high of 50% contingent on the per capita income of the residents. Additionally, although Medicaid is publically funded, care is contracted through the private sector in addition to

FQHCs. Adequacy of networks is a continued problem in contracting with the providers, as well as access to care. As each state controls its own budget, the state therefore needs to be a partner in the incentive discussions. Encouraging primary care practices to become patient centered medical homes, full adoption of an electronic health record and use of electronic prescribing, as well as the ability to share clinical information across the network is critical to the success of an integrated care system. Incentives that assist networks in care coordination, medication therapeutic management and sharing of data across the network are potential areas the states can incentivize.

- 3A. What roles should States play in supporting model design and implementation? As stated above, the states are responsible for almost half of Medicaid costs. States need to be partners in the design if they are paying for the cost of care. More creative reimbursement opportunities combined with business incentives to providers need to be developed. Utilizing the governor's authority as well as the role of the state insurer could align incentives across all payers, and develop more value based contracting would be of great benefit. The model design and implementation of such a design would have to affect enough of a practice panel to change provider behavior. Otherwise, it will not be successful in implementation. Specific roles could include developing and making available to providers an all payer data base, health information exchange, and all payer buy-in to model design.
- 3B. Do States have adequate resources to support an ACO initiative in collaboration with CMS? Yes. The question is the priority of funding needs varies from state to state. Additionally, nationwide systems need to be in place to prevent waste fraud and abuse, and patient enrollment in more than one state. Improvements in Medicaid eligibility need to be addressed.
- 4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? When looking at our network, we have an IT platform that has the capability of connecting all providers of health care services regardless of their means of electronic documentation. Using McKesson Population Manager and Risk Manager, we are able to connect disparate EMRs, practice management systems, insurer claims data,

lab data, and pharmacy data to provide true population health management. We describe population management as two different aspects-coordinated clinical care and coordinated medical management. At the clinical level, the provider is able to see information on patients attributed to the network of providers, diminishing redundancy of services. Additionally, it expands the responsibilities of providing both preventive and chronic disease management beyond the PCP. Every provider has the ability to see what preventive care and chronic disease services are absent from the patient's care, and can affect change by providing, referring, or ordering the services in a more coordinated effort across the network. Our framework of improvement of care is as follows:

I. Medical Management and Care Coordination

St. Vincent's Health Partners, Inc. (SVHP) values efficient, cost-effective, quality healthcare so that patients can embrace and enjoy healthier lives. To improve population health, engaging each patient to participate in his/her care with his/her primary care provider who utilizes medical home processes, allows the "healthcare team" to manage and coordinate care for each patient, each physicians' impanelled patients, as well as the practice group's population. This model will ultimately demonstrate high quality and cost-effective care aligned with patient's participation and choice.
SVHP's goal: to provide the right care, at the right time, using the right resource also summarizes our philosophy. This goal challenges our network to operationalize care coordination through a "playbook" that sets standards and expectation by each member. The playbook defines a standardized approach to managing each transition of care (more than 120), identifies chronic 4 disease and preventative care management requirements, and defines a standard for communication between healthcare team members. The Patient Health Summary is the tool that contains required patient-centric data that facilitates continuous consistent care regardless of location. The Patient Health Summary details the individualized care plan to achieve long-term disease management. To accomplish the goal, SVHP champions improved population health by fundamentally using patient level managed care and organizational coordinated care. The process focuses on three levels of care: the patient at the point of care, the physician-led practice team providing organization and oversight of disease management of its population, and SVHP's attention to chronic disease through registry analysis. This simultaneous three-pronged approach encourages a diversified strategic defined plan to patient care achieving improved population preventive care and chronic disease metrics. The coordinated care approach incorporates health information technology at each

level to effectively enhance patient care translating into population management with high levels of patient satisfaction.
SVHP has the core staff managing the clinically integrated network namely: an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.

In forming our clinically integrated network, software has been purchased and is currently being implemented to connect all the disparate systems across the network so that care can be coordinated at the point of service.

II. IT Integration and the MedVentive Technology Platform

The McKesson MedVentive system is a Knowledge-based technology platform that enables and supports a clinically integrated network. MedVentive's integrated features are supported by a common enterprise data platform, enabling operational efficiencies and data integrity to support coordinated, collaborative care delivery. The MedVentive platform captures and aggregates multiple data sources, including data from numerous electronic health record (EHR) and practice management (PM) systems, to create a truly integrated solution. The MedVentive platform serves two related yet different needs, population management and risk management. The platform is implemented and used at the point of service. Both models are contracted through SVHP at a per physician user annual price, as well as per member per month fee for population health medical and financial management.
The McKesson MedVentive Population Manager Enterprise Quality Registry Platform supports:

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III. Medical Management Services :

Below is an outline of the scope of work for Medical Management provided by SVHP for attributed beneficiaries in the network, augmented by our IT network platform:

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- vi. Disease management
- vii. Predictive modeling
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4A. What are the capabilities of providers in integrating this data with electronic health records? Within our network, our IT system, McKesson Population Manager platform provides the capability to push demographic and clinical data via HL7 (Existing) or Continuity of Care Document (Q4 2014) to provider electronic health records. The data can be integrated and utilized by the provider for clinical decision support via the provider electronic health record at the point of care.

- 4B. What are the capabilities of integrating information for care received in the community or from other non-traditional care providers? Within our network, the McKesson Population and Risk Manager platforms provide the capability to push information received from provider community information systems via an HL7 interface or Continuity of Care Document. The information can be integrated into existing provider information systems to support patient care, population health, and quality/financial reporting.
- 5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures?
  (Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared

savings arrangement that reflects combined Medicare and Medicaid expenditures?) For those networks capable of providing care to both the Medicaid and Medicare population, it would be beneficial to have unified reimbursement models. Allowing a network to combine its Medicare and Medicaid beneficiaries as one combined attribution population could increase the number of ACOs involved in reimbursement model design. Financial arrangements need to provide funds that allow an ACO to pay for current non-reimbursable activities, including care coordination and medication therapy management (MTM). Medicare has published data that estimates initial startup costs of an ACO to be $2 million, while the National Association of ACOs estimates this to be close to $4 million, and AHA has estimated startup costs closer to $11 million. These can cripple both the interest and success of an organization. Consideration of allowing advanced payment model design to help develop the necessary infrastructure capital would allow increased ACO participation. Additionally, ongoing funding through care coordination and MTM would provide the necessary capital for organizations to meet the financial burdens of the infrastructure. Currently, the shared savings occurs 6 months after the close of the year of measurement, requiring ACOs to develop a business model to concurrently fund its operations with delayed potential payments. Removing this burden through advanced payment model and ongoing monthly care coordination and MTM payments to the ACO provides the necessary cash flow and allows the ACO to develop its business model and lead to more appropriate hiring with capital available.

- D. Other Approaches for Increasing Accountability – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.
- A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns.

1. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?

- In assignment of geographically aligned populations, medical services and care coordination can be concentrated and efficiencies can be achieved.
- 1A. What are the most critical design features of a provider-led community ACO model and why? When looking at our network, we have an IT platform that has the capability of connecting all providers of health care services regardless of their means of electronic documentation. Using McKesson Population Manager and Risk Manager, we are able to connect disparate EMRs, practice management systems, insurer claims data, lab data, and pharmacy data to provide true population health management. We describe population management as two different aspects-coordinated clinical care and coordinated medical management. At the clinical level, the provider is able to see information on patients attributed to the network of providers, diminishing redundancy of services. Additionally, it expands the responsibilities of providing both preventive and chronic disease management beyond the PCP. Every provider has the ability to see what preventive care and chronic disease services are absent from the patient's care, and can affect change by providing, referring, or ordering the services in a more coordinated effort across the network. Our framework of improvement of care is as follows:

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1B. What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Rather than add more quality measures, accreditation status should be considered. Currently, there are two national organizations that accredit networks-NCQA and URAC. Each of these agencies has a lengthy list of requirements and capabilities that must be demonstrated by the network to achieve accreditation. Our organization has been accredited for clinical integration by URAC through 2017.

Section 1311(c)(1)(D)(i) of the Patient Protection and Affordable Care Act ("PPACA") requires health plans to be accredited by a recognized accrediting entity in order to be certified as QHPs and operate in the Affordable Insurance Exchanges. On November 23, 2012, the United States Department of Health and Human Services ("HHS") published a *Federal Register* notice announcing that the National Committee for Quality Assurance ("NCQA") and URAC were

recognized accrediting entities for purposes for fulfilling the accreditation requirement for certification of qualified health plans ("QHPs"). Patient Protection and Affordable Care Act (PPACA) contains various provisions that support implementation of the medical home model including new payment policies, Medicaid demonstrations, and the creation of Accountable Care Organizations. As URAC and NCQA both have programs for PCMH recognition/certification, we would recommend within 3 years of being accepted as an ACO, an organization must achieve recognition by NCQA or URAC. Otherwise, it cannot be a continued recognized ACO, and must gain accreditation prior to being re-accepted by CMS.

1C. Are there models to consider that better integrate community-based services beyond the traditional medical system? The traditional medical system is fractionated, episodic and uncoordinated. Encouraging coordination of care across all transitions of care through clinical integration of providers, and demonstrating **true transformation of care through the provider practice and clinically integrated network** is necessary. This can be achieved using accreditation of both the patient centered medical home and ACOs/Clinically Integrated Networks as a model for continued participation in these reimbursement models. This provides outside validation of the practice/network capabilities, and provides the beneficiary knowledge of the capabilities of the organization. Currently, many practices state they are patient centered or clinically integrated, yet have not sought accreditation/recognition nor had their statements validated through an accrediting body.

Principles of Patient Centered Medical Homes

In 2007, the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Physicians, and the American Osteopathic Association released "Joint Principles of the Patient-Centered Medical Home." In it they distilled the following seven principles of the medical home. They are, in part:

1. ***Personal physician*** – each patient has an ongoing relationship with a personal physician trained to provide first contact, continuous and comprehensive care.

2. ***Physician directed medical practice*** – the personal physician leads a team of individuals at the practice level who collectively take responsibility for the ongoing care of patients.

3. ***Whole person orientation*** – the personal physician is responsible for providing for all the patient's health care needs or taking responsibility for appropriately arranging care with other qualified professionals. This includes care for all stages of life; acute care; chronic care; preventive services; and end of life care.

4. ***Care is coordinated and/or integrated*** across all elements of the complex health care system (e.g., subspecialty care, hospitals, home health agencies, nursing homes) and the patient's community (e.g., family, public and private community-based services). Care is facilitated by registries, information technology, health information exchange and other means to assure that patients get the indicated care when and where they need and want it in a culturally and linguistically appropriate manner.

5. ***Quality and safety*** are hallmarks of the medical home.

6. ***Enhanced access*** to care is available through systems such as open scheduling, expanded hours and new options for communication between patients, their personal physician, and practice staff.

7. ***Payment*** appropriately recognizes the added value provided to patients who have a patient-centered medical home.

Four organizations that offer PCMH recognition or Accreditation are:

- National Commission for Quality Assurance (NCQA)
- The Joint Commission in conjunction with its Ambulatory Care Accreditation
- Accreditation Association for Ambulatory Health Care
- URAC

We recommend consideration of a requirement within the first 3 years of contracting with CMS primary care practices in an ACO must achieve accreditation/recognition by one of these national entities, or state programs such as Physician Group Incentive Program (PGIP) PCMH designation recognized in Michigan.

Currently, NCQA accredits ACOs, and URAC accredits both ACOs and clinically integrated networks. Additionally, the FTC provides a formal advisory opinions on whether an organization meets its standards for clinical integration.

NCQA ACO Accreditation helps health care organizations demonstrate their ability to improve quality, reduce costs and coordinate patient care. Built from our successful

patient-centered medical home (PCMH) recognition program, NCQA's ACO standards and guidelines incorporate whole-person care coordination throughout the health care system.

URAC Clinical integration accreditation demonstrates the network is capable of the coordination of patient care across conditions, providers, settings, and time to achieve care that is safe, effective, efficient, and patient focused. Clinical integration focuses on provider collaboration to ensure best practices consistent with evidence-based guidelines and coordination to deliver cost-effective, quality care.

Clinical integration requires providers to work together to share clinical data within a framework and network more expansive than a medical home, with the shared goal of rendering necessary care to patients in an efficient manner with the best possible outcomes. Successful clinical integration requires collaboration and coordination at all levels of the network, and URAC's Clinical Integration Accreditation sets the framework for the type of collaborative environment that controls costs, ensures quality, and improves health outcomes.

URAC's ACO accreditation demonstrates the ACO's are committed to improving population health, enhancing the total patient experience of care, and reducing per capita cost, and they achieve that by assuming greater financial risk through management of their patient populations.

All ACO's are underpinned by a clinically integrated network that ties together all of the clinical components needed to serve a given population, and URAC's accountable care program provides accreditation for the most advanced, ACO-ready networks.

We propose that ACOs achieve accreditation through NCQA or URAC as either an ACO or clinically integrated network, or receive a favorable advisory opinion from the FTC as meeting clinical integration within the first three years of participation in a CMS ACO reimbursement model for continuation. Our organization is the first in the country to achieve the URAC Clinical Integration Accreditation, effective March 1, 2014.

- In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives.

2. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?

Yes

- 2A. More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments?
  Yes, depending on how episode based payments are defined.
- 2B. If so, what would the most critical features of such a "layered" ACO be and why? First, CMS should consider reinstating the advance payment model. Recent studies published from the National Association of ACOs report that the estimated cost of starting an ACO is close to $4 million. This is extremely difficult to fund in the current FFS model. By providing advanced payments to organizations, and requiring the ability to obtain accreditation within a specific timeframe to continue as an ACO, networks can more successfully develop the infrastructure and provide quicker improvements in quality of care and decreased costs. Second, providing care coordination fees on a pmpm basis allows the ability to provide care coordination services, negating the need to develop new billing codes to achieve this. It is also less an administrative burden. Third, providing MTM reimbursement on a pmpm basis. MTM would include oversight of medication adherence, medication reconciliation, medication interaction prevention, provider education to allow replacement of brand name medication for a generic equivalent, or lower cost same or similar class medication, and oversight of unnecessary duplication of prescribing same or similar medications. In a project in North Carolina, there was a return of $13.5 for each dollar spent on Part D with such an MTM program. Finally, consider reimbursement of point of care FFS for primary and certain specialty care services based upon practice wide quality metrics Consider differential FFS basis of reimbursement based upon meeting or exceeding 25th, 50th, 75th and 90th percentiles. Finally, shared savings, with the need to demonstrate a threshold of quality, with splitting of the first dollar saved. The current model creates a minimum 2.5% threshold to discount for statistical variation, further burdening a network to achieve more with less. Practices have to invest in practice transformation, yet are not rewarded until a minimal threshold of savings is met. This is a discouragement for practices investing in clinical integration, as incremental changes are required within a practice, and incremental savings should be expected. A consideration can be made

that after three years, certain threshold must be met, allowing for reimbursement of the development phase in the first 3 years with first dollar saved. If there are any savings, regardless of threshold, practices should receive first dollar saved.

- E. Multi-Payer ACOs – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement.
- 1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs? Work with state insurers to develop state specific models of design. It either needs to be legislated, decreed by the governor, or a requirement through the state insurance departments. Tying increase in state funding through CMS to support Medicare and Medicaid if such models are developed would provide incentives for states to move to ACO design models.
- 2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden? This requires several simultaneous strategies. The first is to align all quality metrics among insurers. This can be done at the state insurance level, with each state selecting metrics that must be aligned by all licensed insurers. Insurers can choose more, but all must be required to be aligned on a threshold of quality metric alignment. Second, provider access to real-time accurate actionable data in regards to the metrics to make them meaningful and allow for provider behavioral change. Third, change the reimbursement model. Using the FFS as a basis of which providers are very familiar, reward the FFS based on a grouping of all payer quality metrics, providing a practice provider specific annual score. FFS reimbursement can be tiered based upon meeting or exceeding 25th, 50th, 75th and 90th percentile scores, or level of improvement if under 25%. Directly tying reimbursement to quality based upon tiered thresholds will provide the greatest incentive to transform practices.

Steward Promise
A Medicare Pioneer ACO

RFI RESPONSE | FEBRUARY 28, 2014

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SECTION I

Section A:

1. ***Would additional health care organizations be interested in applying to the Pioneer ACO Model?***
   - ***Yes or No***
   - ***Why or why not?***

Steward's Response: (text box limited – 255 spaces)
None

2. ***If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?***

   Limit the number of selected organizations or Accept all organizations that meet the qualifying criteria.

Steward's Response:

Limit the number of selected organizations

What are the advantages and/or disadvantages of either approach?

Steward's Response: (unlimited)

Steward Health Care is committed to delivering high quality care, reducing expenditures, and improving the overall health of all members in the communities we serve, and we fully support CMS' efforts to develop a sustainable model of care for all Medicare beneficiaries. As the first phase of performance results from the Pioneer and the Medicare Shared Savings programs demonstrate, health care delivery system transformation can help achieve the triple aim. CMS' innovative risk-based payment models like the Pioneer ACO and MSSP programs have catalyzed the adoption of integrated care models and created one pathway to ensure the long-term viability of the Medicare program. Within this landscape, we are encouraged by CMS' continued commitment to transition away from fee-for-service models and we are grateful for the opportunity to submit these comments in response to the request for information.

CMMI should also be commended for its ongoing efforts to identify best practices amongst Pioneers and other exemplary ACOs to address issues which persist in the current model. While we fully support the rapid adoption of integrated care models, CMS and CMMI must acknowledge that rapid scale must be met with similarly aggressive tactics to address key financial, operational, and policy challenges that threaten the sustainability and participation of Pioneer ACOs in this program.

Steward has invested millions of dollars to develop and maintain an infrastructure for supporting our Community Care model aimed at providing high quality and efficient care for our Medicare beneficiaries in their communities. Steward's Pioneer program is run efficiently relative to medical spend with operating expenses representing less than 2% of our Pioneer global budget.

Despite Steward's efficient operations and an outlook for even greater projected savings in performance year 2 compared to year 1, the continued viability of the program is threatened by program risks that inhibit the ability of all Pioneers to accurately project performance and to adapt the population health management programs based on predictable models.

CMMI must make immediate programmatic changes and improvements not only to assist existing providers to continue to successfully drive savings, but also to administer patient care in an efficient and integrated manner. In addition, CMMI must implement modifications that assist providers to better coordinate care and reasonably predict the cost, performance, and patient attribution of each provider participant in order to ensure the success of the program. The existing program's structure makes it very difficult for providers to predict their performance, which threatens the ability of all Pioneers to justify continued participation and may inhibit new providers from participating in the program.

Before accepting additional qualified ACO participants, we encourage CMS/CMMI to work with existing Pioneers to develop solutions that address risks to the ability for Pioneers to develop a sustainable and predictable model.

Examples of such risks to be addressed collaboratively between CMS/CMMI and Pioneers:

1) **Projecting financial performance**
    a. High sensitivity to decedent weight adjustment resulting in high volatility in benchmark projections, including wide shifts in benchmark value and overall performance resulting from health status changes of a small number of aligned beneficiaries.
    b. Population health efforts to reduce mortality have an unpredictable and/or large impact on the benchmark calculation.
    c. Inability to tie monthly claims lag tables with quarterly performance reports
    d. Disparate reporting of beneficiary counts from monthly to quarterly reports
    e. Delayed performance reports (e.g., preliminary 2014 baseline reports due to possible gaps in historical TINs) may require a Pioneer ACO to delay operational decisions and sustain continued costs that might have been avoided.
    f. Changes in methodology (decedent weight impact) similarly delay Pioneer risk track elections and decisions to continue participation, forcing Pioneers to incur ongoing operating costs that might otherwise have been avoided and hindering projections of performance.
    g. Announcements of changed methodology or calculations that occur late in the performance year, precluding informed decision making prior to the opt-out deadline.

2) **Predictability in the timing of program enhancements**

a. Implementation delays in Pioneer program enhancements (e.g., SNF Waivers) limit the ability to manage expenditures and diminish accuracy of internal projections built around original timelines.

3) Projecting quality performance

a. Quality benchmarks released for PY2 (2013) two days before the end of the performance year (12/30/2013).
b. Lack of transparency in developing benchmarking standards or results of audit
c. Limited engagement of Pioneers to leverage resources and knowledge in quality improvement
    i. No forum to share best practices and standards for performance improvement
    ii. No follow through with facilitating quality measurement and benchmarking discussions.
d. Numerous revisions in guidance related to quality metrics have created doubt related to final implementation
e. Limited engagement with Pioneers about the quality metric definitions and benchmarks

4) Projecting Membership and Beneficiary Turnover

	Beneficiary turnover	**Retained Beneficiaries from Previous Performance Year**	**New Beneficiaries in New Performance Year**
PY1 to PY2	11,000	24,000	24,000
PY2 to PY3	10,000	35,000	30,000

Finally, given that establishing a more sustainable model is contingent upon improving the predictability of both performance and membership, we recommend CMS/CMMI not add any new ACO participants where a dense population of Medicare beneficiaries are already being cared for by existing Pioneer ACOs and MSSP participants unless there is an open, clear and transparent process for patient - primary care physician attestation. Allowing new applicants in eastern Massachusetts, for instance, under the current program structure would further exacerbate the turnover and patient disruption risks outlined above by lessening the ability of existing Pioneers to coordinate care, project membership, and improve clinical and financial performance.

CMMI must recognize that each Pioneer must justify continued participation through generation of an annual net operating surplus or sufficient reassurance that current investments in infrastructure and population health will yield sufficient returns in future years through the Pioneer program or its successor. We offer these comments in the hope that CMMI will continue to evolve the program to meet the needs of our patients and the Medicare program at large and to further transition Medicare away from fee for service models toward risk-based, population based payments. However, we are concerned that without the improvements outlined above, the addition of new participants will jeopardize the program's long-term success.

3. ***Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?***

Steward's Response: (text box limited – 255 spaces)
Require PCP selection to ensure coordinated care & appropriate utilization of services. Administer PBPM fee to ACOs to support infrastructure investments and allow ACOs to take on full risk and be rewarded for achieving value (high quality w/ lower trend).

Section B: Population Based Payments

1. ***Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP?***
    - ***Yes or No***
    - ***Why or why not?***

Steward's Response: (text box limited – 255 spaces)
ACOs need the option to select differential FFS reduction amounts by Provider type to support a range of provider engagement incentives & strategies across the continuum of care (i.e. ambulatory primary & specialty-care, acute, post-acute settings, etc.)

2. ***Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?***

    Why or why not?

Steward's Response: (text box limited – 255 spaces)
Yes.
ACOs should have the option to reduce FFS payment to any Medicare provider/supplier that agrees to participate regardless of whether that provider/supplier is included in the ACO's annual provider/supplier list submission.

3. ***Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves?***
    - ***Yes or No***
    - ***Why or why not?***

Steward's Response: (text box limited – 255 spaces)
Yes.
Meeting specified level of savings should not be a requisite for PBP because of ongoing issues with the settlement methodology and the unpredictability of beneficiary turnover. PBPs should also include care management fees to support coordination efforts.

4. ***Should any additional refinements be made to the current Pioneer ACO PBP policy?***
    - ***Yes or No***

- ***Why or why not?***

Steward's Response: (text box limited – 255 spaces)
Yes.

ACOs should have the option to select full risk & PBP up to 100% of part A & B under any risk track. The 3% discount for PBP should be eliminated or ACOs should be able to establish a reserve from discounted FFS payments or receive an infrastructure fee.

SECTION II

Section A: Transition to greater insurance risk

1. ***Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?***

Steward's Response: (text box limited – 255 spaces)
Steward embraces the opportunity for full risk as a pathway to address Medicare's fiscal and structural challenges. This delegation of risk must be accompanied by programmatic changes similar to MA that empower care coordination efforts.

2. ***What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)***

Steward's Response: (text box limited – 255 spaces)
Steward would support the option to assume full insurance risk including part A, B, D, and Medicaid under circumstances that incorporate PCP selection and address current operational and program challenges which expose ACOs to inordinate risk.

3. ***Are there services that should be carved out of ACO capitation? Why?***

Steward's Response: (text box limited – 255 spaces)

Steward believes all services can be included in ACO risk arrangements when supported by a robust financial model, operational efficiencies, and appropriate policy options.

4. ***What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?***

Steward's Response: (text box limited – 255 spaces)

Pioneer ACOs should have waiver protections to engage with non-ACO post-acute care providers and part D plans to negotiate specific discounts, develop program enhancements, or share two-sided risk in support of the ACO's efforts to meet the triple-aim.

5. ***What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would not be appropriate for ACOs assuming full insurance risk?***

Steward's Response: (unlimited)

Pioneer ACOs currently face regulatory and compliance framework restrictions that contribute to Medicare beneficiaries not receiving high quality and efficient care which would be available if such restrictions were amended. Any ACO or risk-based model depends upon a meaningful relationship between patients and physicians. Therefore a key component of any successful health care model must be the opportunity for patients to choose a primary care provider (PCP) or have access to a PCP that can coordinate the majority of their care.

Currently, Medicare FFS beneficiaries do not need to select a PCP to coordinate their care. This leads to increased medical utilization, higher costs, and inefficiency. Medicare can and should implement PCP selection criteria for all FFS beneficiaries, encouraging coordinated primary care and appropriate utilization. The selection of PCPs will also aid in beneficiary alignment in ACO and risk-based models, as Medicare seeks to achieve value-driven health care for beneficiaries. The PCP selection could be associated with enhanced benefits to ensure that the policy is not construed as a limitation of beneficiary choice.

In addition, PCP selection provides additional stability for ACOs who have experienced tremendous beneficiary turnover each performance year. This ensures beneficiaries can retain the full benefit of coordinated care and services while allowing ACOs to invest time and resources that ensure its long-term viability.

To further facilitate meaningful relationships between patients and physicians, restrictions that limit a provider's and an ACO's ability to identify a Pioneer beneficiary at the point of care should be amended. This includes the overly prescriptive guidance by CMS/CMMI for Pioneer beneficiary identification cards that misses an opportunity to present the positive benefits of the Pioneer ACO and rather reinforces the rules of the Medicare program, which is an unconvincing way to encourage partnerships between physician and patients.

CMS should also eliminate the restriction imposed on ACOs from offering to beneficiaries the choice to remain in a particular ACO during the Medicare annual enrollment period. To truly honor a patient's preference for care, ACOs should have equal access to discuss and present the benefits of remaining a FFS beneficiary aligned with the ACO. The current restriction contributes to an ACO's experience with significant beneficiary turnover each year due to aggressive Medicare Advantage marketing campaigns and limits the ability of the patient to make an informed decision.

Another restriction that should be lifted immediately in order to maximize patient choice for high quality and efficient care includes the requirement for a three-day inpatient stay prior to receiving SNF benefits. ACOs should have the option to apply the three-day waiver more broadly to offer Medicare FFS beneficiaries better care that aligns with clinical standards and regulatory allowances for Medicare Advantage plans.

Importantly, this must also be supplemented by allowances for ACOs to create arrangements with preferred providers across the continuum of care that are based on improving quality and efficiency and

include financial discounts or case rates based on performance. Explicit guidance for these proposed arrangements is crucial to ensure that all ACOs function within appropriate constraints while fostering the innovation required to promote the triple aim.

Lastly, while we commend CMS/CMMI's desire to align the Pioneer ACO model with the Medicare Shared Savings Program quality program, problems due to vague descriptions in narrative specifications, clinically inappropriate requirements in the quality measures, and non-transparent development of benchmarks cannot be addressed in a timely manner due to the quality program's tie to the Physician Fee Schedule regulation. This could be addressed immediately through the adoption and alignment with CMS' existing Medicare Five-Star quality program which benefits from broad acceptance, familiarity, and robust benchmarking data.

The alignment of compliance and regulatory requirements across Medicare Advantage and Pioneer ACO programs places a strong foundation for ACOs to transition to full risk bearing entities that can compete with Medicare Advantage plans. Beyond the five-years contemplated for the Pioneer model, ACOs looking to continue to foster physician and beneficiary engagement to improve quality and bend the cost curve need the ability to reap the long-term benefits of population health and care management investments. To that end, CMS should allow ACOs to have preferential beneficiary engagement opportunities when ACOs elect to transition to another integrated care model or Medicare Advantage strategy. Development of a transition strategy ensures that ACOs can continue to deliver value to the Medicare program through sustained investment in population health strategies for aligned beneficiaries.

6. ***What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?***

   Steward's Response: (unlimited)

As state licensing agencies such as the Massachusetts Division of Insurance considered new regulations for risk-bearing entities, ACOs potentially face overly burdensome requirements that would severely limit participation in integrated care models such as the Pioneer program. ACOs should be governed by regulations that stipulate a new and flexible framework for evaluating provider risk in a continuously evolving market place, without adding costly, burdensome, and unnecessary administrative rules. In particular, initial requirements should avoid stringent and expensive requirements for acquisition of previously licensed entities or formation of large capital reserves that would drain resources that could be better applied to infrastructure or population health investments. To this end, we strongly encourage states to adopt Risk-Bearing Provider Organization (RBPO) standards that are aligned with the flexible, innovation-friendly standards utilized by the federal government for its risk-based alternative payment demonstrations.

For example, organizations should be certified or receive waivers to bear risk at the parent level. To ensure that the parent is appropriately safeguarding children from potential financial exposure, we recommend parents provide a specific list of its child organizations. Where one or more of the children

may have direct risk contracts, the application could be accompanied by a detailed description of the actions taken by the parent to either protect the children organizations from financial exposure.

At minimum, we believe that a parent organization seeking waiver protection or certification to bear risk should be able to demonstrate (1) knowledge and approval of the risk arrangement; (2) reporting to a parent governance entity regarding ongoing performance under such risk-based arrangement or contract; and (3) attestation regarding the parent's ultimate accountability for losses sustained through risk arrangements, or some form of attestation by the parent regarding maintenance of sufficient reserves or other access to financial protection sufficient to cover potential losses by children.

7. ***Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?***

Steward's Response: (text box limited – 255 spaces)

Infrastructure payments should be made to all ACOs to support expanded member engagement and customer service functions, supported by cost savings from consolidating all Medicare (FFS and MA) claims data processing and reporting into regional contractors.

8. ***What are approaches for setting appropriate capitation rates?***

Steward's Response: (unlimited)

ACOs should be responsible for managing the quality, utilization, and total medical expenses of all health care services including primary, specialty, pharmacy, ancillary, and hospital care provided to its attributed population. Using the attributed population's baseline year health-status adjusted total medical expenses, the budget target can be set by adjusting for health status and budget trend using the regional Medical Consumer Price Index (CPI) for each ACO. The budget should exclude out-of-area services. A Per Beneficiary Per Month (PBPM) capitation payment should reflect the projected budget and adjusted to include additional care management fees to fund care management and coordination efforts.

The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

Steward's Response: (text box limited – 255 spaces)

Massachusetts ACOs are disadvantaged when using the absolute dollar of national expenditure growth for benchmarking due to the differential cost of care compared to the local region. Instead ACOs should be held to % trend or regional expenditure trends.

9. ***What are the advantages or disadvantages of different strategies for risk-adjustment? (Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)***

Steward's Response: (text box limited – 255 spaces)

The Pioneer program's current demographic risk adjustment is overly sensitive to mortality rates. Risk adjustment based on diagnosis coding, used in Medicare Advantage, may facilitate greater clinical engagement between physician and patient.

10. ***What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?***

Steward's Response: (text box limited – 255 spaces)

Benefit enhancements such as reduced or tiered cost-sharing for beneficiaries would support greater patient-physician decision-making, increased data integration, care coordination, and utilization of services while fully retaining patient choice.

11. ***What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?***

Steward's Response: (text box limited – 255 spaces)

As ACOs move to full risk, the key program integrity issue will be that many beneficiaries will not know they are being cared for by an ACO. We think the best way to address this is to offer an incentive to beneficiaries to select a PCP.

12. ***What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?***
    Steward's Response: (unlimited)

ACOs should be permitted to craft programmatic elements as benefit enhancements to ensure that there is no direct limitation of beneficiary freedom of choice. Requiring all Medicare beneficiaries to affirmatively select their preferred PCP is a critical step for protecting beneficiaries and limiting the potential for confusion for patients, providers, and ACOs. Patient who elect a PCP or who submit to the requirements for referrals could receive enhanced benefits in the form of reduced cost-sharing or non-monetary, health-related benefits targeted to addressing specific health conditions or overall health/lifestyle. The current restriction which limits ACOs from contacting Pioneer beneficiaries during Medicare's annual enrollment period must be lifted to ensure beneficiaries understand the opportunity to retain greater freedom of choice by choosing an ACO over a Medicare Advantage plan.

13. ***Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?***
    Steward's Response: (text box limited – 255 spaces)

CMS should require all Medicare FFS beneficiaries to affirmatively select their preferred PCP. In addition, beneficiaries who are not aligned to a Pioneer ACO from claims-based algorithms should have the option to attest to alignment with an ACO.

Section B: Integrating accountability for Medicare Part D Expenditures

1. ***Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?***

Steward's Response: (unlimited)

Steward recommends that Medicare allow for providers and ACOs to compete with Managed Care Organizations directly for beneficiaries. This competition will further drive value to Medicare and Medicare patients who have come to expect high quality services from providers.

In addition, CMS should provide ACOs with comprehensive aggregated data showing the relative volume of participation across various Part D sponsors/pharmacy benefit management companies for the ACOs aligned beneficiaries. This can be accomplished by CMS inviting public-private payer collaboration with meaningful data sharing with ACOs to efficiently evaluate the opportunities of establishing various arrangements, including with Part D sponsors/pharmacy benefit management companies.

What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

Steward's Response: (text box limited – 255 spaces)

CMS should ensure programs are supported by robust financial models, operational efficiencies, and policy options that allow ACOs to maximize performance and ensure continued viability and participation.

2. ***Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?***

Steward's Response: (text box limited – 255 spaces)

Steward is interested in opportunities to accept risk that provide value to Medicare and Medicare beneficiaries. Part D risk should be offered to ACOs with tiered risk levels until requirements or risk algorithms are vetted.

3. ***Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?***

Steward's Response: (text box limited – 255 spaces)

ACOs would need more robust Part D data to assume full risk on Part D expenditures and should have the option to elect tiered risk level arrangements ranging from upside only to full risk.

Section C: Integrating accountability for Medicaid Care Outcomes

1. ***CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?***

Steward's Response: (text box limited – 255 spaces)

CMS should adopt Medicare program and administrative features for the Medicaid program to provide more robust data required to support risk-based models and to support more efficiently run programs. This alignment is critical for ACOs to assume risk.

2. ***What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?***

Steward's Response: (unlimited)

CMS should prioritize addressing policy and operational challenges in Medicare and Medicaid programs to ensure any delivery system and payment reform models, including accountability for Medicaid, duals, CHIP, and/or geographic community-based models, have foundational elements to ensure Medicare's long-term viability. These fundamental elements include the requirement for beneficiaries to affirmatively select a PCP, including infrastructure and management fees in capitation payments to providers, aligning claims data and reporting across Medicare and Medicaid programs, allowing ACOs to compete with Managed Care Organizations for beneficiary engagement, and minimizing administrative burdens or redundant requirements.

3. ***What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?***

Steward's Response: (text box limited – 255 spaces)

States should support the adoption of Medicare program and administrative features for the Medicaid program. This will support greater alignment across all risk-based models, regardless of payer.

What roles should States play in supporting model design and implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

Steward's Response: (unlimited)

First, CMS and the States must address the growing disparity in reimbursement rates for Medicaid payments. In addition, CMS should collaborate with state Medicaid agencies to discourage any efforts to establish programs or demonstrations that are siloed from federally sponsored programs such as the Pioneer model. Ideally, CMS can help ensure that any Medicaid ACO model is built around consistent foundational elements including a standardized quality program and consistent financial/operational methodologies which will help facilitate Pioneer ACO entry and participation. This will ease administration of the program and facilitate experience sharing between ACOs across state lines. States can encourage greater adoption and implementation by ensuring greater alignment and convergence of

requirements that supplement an ACO's ability to manage a population. States may not have adequate resources to develop a new or home-grown Medicaid ACO program without recapitulating previous updates and modifications necessitated by growing experience administering an ACO.

4. ***What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?***

Steward's Response: (unlimited)

While ACOs build tremendous claims and clinical data analytic capabilities for commercial and Medicare data, Medicaid data is less robust and reliable for driving care improvement and supporting performance reporting. Medicaid should adopt Medicare program and administrative features to ensure greater alignment and support for delivery systems adopting risk.

What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

Steward's Response: (text box limited – 255 spaces)

Integrating timely and actionable data from non-ACO providers continues to be a challenge for ACOs. A management fee would promote further investment in data integration.

5. ***What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?***

Steward's Response: (text box limited – 255 spaces)

Performance should be accounted for separately for Medicaid-only and Medicare-only populations to distinguish expenditures trends and interventions. Programs should aim for uniformity in underlying methodologies and reporting requirements, as possible.

Section D: Other Approaches for Increasing Accountability

1. ***A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?***

   Steward's Response: (unlimited)

   While episode-based care focused on certain high-cost procedures and indexed from inpatient facilities, as seen in CMS' Bundled Payment for Care Initiative, represents a cost savings opportunity for the Medicare program, beneficiaries with access to expensive academic medical centers in their region will continue to seek care for more than 60% of routine care at these sites despite comparable quality at local community hospitals.

Provider-led community ACOs need to be complemented with patient-centered care that fosters greater physician-patient decision making. This can be accomplished with key benefit enhancements tied to a beneficiary's affirmative selection to their preferred PCP.

Offering benefit enhancements such as lower co-pays or deductibles for incurred services and discounted premiums for Part D and Medicare Supplemental plans and tiering providers (i.e. community and non-community) based on quality and cost will encourage greater utilization of high-value providers (high quality, cost efficient, community-based providers). This has the benefit of yielding immediate cost savings to the Medicare program while providing enhanced choices to beneficiaries. In addition, this approach mitigates the regressive nature of health care, as more affluent individuals tend to utilize more services at higher priced facilities.

Tiering will also bring greater transparency to the Medicare payment system and serve to educate the community and public at-large regarding the trade-offs between high quality cost efficiency providers versus more expensive providers with comparable quality.

Beneficiary residence within an ACO service area should NOT be used as the sole or dominant model for aligning beneficiaries, particularly in areas with multiple ACOs whose services areas overlap.

What are the most critical design features of a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

Steward's Response: (text box limited – 255 spaces)

Affirmative PCP selection, tiering provider based on cost and quality, full-capitated risk, and allowing ACOs/Providers to compete with Managed Care Organizations for beneficiary engagement.

2. ***In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?***

Steward's Response: (text box limited – 255 spaces)

ACOs should have the option to use existing infrastructure to maximize performance in all risk contracts. Current CMS service & payment reform initiatives expose ACOs to risks from redundant admin requirements and insubstantial performance opportunities.

Section E: Multi-Payer ACOs

1. ***How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?***

Steward's Response: (text box limited – 255 spaces)

Advance more public-private collaboration as seen in CMMI's CPCI program. This could leverage existing claims processing and analytic infrastructure to provide efficiency to Medicare and robust data reporting on cost, utilization, and quality to ACOs.

2. ***How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?***

Steward's Response: (text box limited – 255 spaces)
CMS should immediately adopt the well-established Medicare Five-Star program for ACOs. Eventually, ACOs should also have the option to replace metrics with those from clinical integration programs which may cross all-payer type contract arrangements.

The Academy Advisors

March 1, 2014

VIA ELECTRONIC MAIL & U.S. MAIL

The Honorable Marilyn Tavenner
Administrator
Centers of Medicare & Medicaid Services
U.S. Department of Health & Human Services, Room 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Centers for Medicare & Medicaid Services Request for Information related to the evolution of Accountable Care Organization initiatives

Dear Administrator Tavenner:

We write to you under the banner of The Academy Advisors[i], a policy coalition associated with The Health Management Academy[ii], to express our response to the Centers for Medicare and Medicaid Services ("CMS") Request for Information ("RFI") seeking input related to the evolution of Medicare Accountable Care Organization ("ACO") initiatives. Our Leading Health Systems are providers of integrated care across the United States, dedicated to patient and community care, and on the leading edge of medical research, education and training.

Since the inception of the Pioneer ACO and Medicare Shared Savings Program ("MSSP") ACO model, health care providers across the United States have engaged in care coordination resulting in better health for communities, better care for individuals and a reduction in the growth of health care expenditures. ACOs affiliated with The Academy Advisors health systems have almost 1.5 million lives attributed to Medicare and commercial ACO programs. We are committed to a partnership with CMS that provides care coordination across the continuum and enhanced health outcomes for Medicare beneficiaries.

The current Pioneer ACO and MSSP ACO programs have been successful in transitioning health care providers into "population health" models, delivering patient-centered care to Medicare beneficiaries. While both the Pioneer and MSSP ACO models have experienced success, we believe there are modifications which can be incorporated into the next generation of ACOs that will lead to increased participation and improved patient outcomes. We write to suggest some of these modifications which will lead to enhanced integration and coordination among providers, increased financial accountability and superior quality and efficiency for Medicare beneficiaries.

In the spirit of constructive feedback, we will focus our suggestions for the next generation of ACOs on the following policy proposals:

1) **Beneficiary Attribution**: In the final rule for the MSSP ACO model, CMS adopted retrospective beneficiary attribution.[1] Retrospective beneficiary attribution, while providing enhanced certainty for shared-savings calculations, fails to provide ACO participants with the time and advance notice to best prepare for addressing the care of Medicare beneficiaries assigned to the ACO. Leading Health Systems strive to provide an unsurpassed level of care for all patients, all the time. However, as Leading Health Systems continue to expand coordinated care networks and engage beneficiaries, the success of the Medicare ACO programs will be predicated on substantial beneficiary engagement with providers. Prospective attribution best allows Medicare ACOs to achieve a high level of beneficiary engagement.

Recommendation: We recommend that the Medicare ACO programs adopt prospective attribution, as it places the patient in a more influential position to impact the care process while simultaneously offering providers the opportunity to prepare and implement an appropriate care plan for each Medicare ACO beneficiary.

[1] 76 Fed. Reg. 67862 (Nov. 2, 2011)

2) **Performance Benchmarks**: For the next cohort of Medicare ACOs, performance benchmarks should be based on health care spending in regional or local geographic areas and Medicare ACOs who incur spending per beneficiary below these benchmarks should not be faced with an increasingly lower benchmark moving forward. Performance benchmarks based on regional or local health care spending would speed the expansion and adoption of the Medicare ACO programs, and eliminate the concern that Medicare ACO participation will lead to a "downward spiral" whereby generating enough savings in the future to incur "shared savings" becomes impossible. Furthermore, the current MSSP ACO catastrophic claims are also subject to a national reference population, as opposed to local or regional geographic benchmarks.

Recommendation: We recommend that CMS evaluate and consider regional and/or local geographic performance benchmarks for Medicare ACOs and catastrophic claims, and that CMS consider keeping benchmarks stable for Medicare ACOs who incur spending below a regional and/or local geographic performance benchmark.

3) **Beneficiary Communication**: Medicare ACOs are currently restricted with regard to how they are permitted to communicate with attributed beneficiaries. While protection of Medicare beneficiaries is and should remain a primary concern, a heightened degree of communication with beneficiaries within specific bounds will reduce the likelihood of confusion and increase the ability to actively engage in care coordination activities. Currently, Medicare ACOs are required to submit marketing materials to CMS, which can then disapprove the marketing materials at any time, including after the expiration of an initial 5-day review period. Additionally, while ACOs are required to "use template language developed by CMS, if available[2]" the forms and language developed by CMS are often overly complex, resulting in substantial confusion and misdirection for Medicare beneficiaries. Increasing the frequency of communication and permitting Medicare ACOs to have an expanded role in developing their own communication strategies will result in higher beneficiary engagement, less confusion, and improved participation between Medicare beneficiaries and health care providers.

Recommendation: We recommend that CMS establish basic beneficiary communication concepts for Medicare ACOs to follow which are not overly prescriptive, but at the same time provide adequate safeguards for Medicare beneficiaries. Further, we suggest that Medicare ACOs be allowed to edit any CMS marketing template within the spirit of the Medicare ACO programs and pre-determined parameters.

4) **Data & Information Transfer**: A well-functioning ACO must utilize, transmit, connect and distribute data in a robust manner. Through the first phase of both the Pioneer and MSSP ACO programs, Medicare ACOs have received untimely and incorrect data. It is difficult for Medicare ACOs to maximize the impact of care coordination if they are unaware of adverse events impacting the health of a particular Medicare beneficiary. Timely and accurate data are important to the long-term success of the Medicare ACO models.

Recommendation: We recommend that CMS deliver data in standardized file formats on a regular, periodic schedule and that upon the discovery of an error, CMS immediately notify ACOs of corrupted data.

5) **Fraud & Abuse Waivers**: Many of the Leading Health Systems who participate in the various Medicare ACO programs are also participants in ACOs or shared risk arrangements with commercial health plans, applying the same standards of care and implementing the same care coordination methods. The lack of fraud & abuse waivers applicable to ACO arrangements with commercial payers creates organizational confusion and general restraint in incorporating each of the different organizational coordination strategies which could be used to maximize care to Medicare beneficiaries. Additionally, the absence of any waiver which preempts state law fraud and abuse programs creates additional hurdles to full implementation of coordinated care initiatives.

[2] 42 CFR 425.310(c)(1)

Recommendation: We recommend the application of Medicare ACO fraud and abuse waivers to commercial ACOs, and the adoption of regulations which would preempt any state fraud and abuse regulations which could discourage ACOs from fully implementing the full spectrum of coordinated care solutions for Medicare beneficiaries.

We believe that these issues comprise the foundational modifications necessary to ensure success and increase participation in the next generation of the Medicare ACO programs. Leading Health Systems have encountered numerous financial, structural and technological hurdles in the journey to providing accountable care. This is true even for systems who were previously operating as highly integrated care coordination networks. Enhanced participation and continued evolution toward complete population health management will be possible if the foundational issues addressed herein are reflected in the next generation of Medicare ACOs.

Many of our health systems anticipate providing comments and feedback to CMS, either independently or in collaboration with other policy groups, specifically setting forth more extensive and technical recommendations than those included in this correspondence. However, we believe that it is important to address these foundational issues regarding the next generation of ACOs. We do this with the optimism that CMS will continue its focus of making the Medicare ACO program a success for patients, providers, and all participants, guaranteeing the future success of a program that delivers care coordination and continuum of care health management to Medicare beneficiaries.

Yours sincerely,

The Academy Advisors

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By: Nathaniel M. Bays, III
General Counsel & Executive Director, Health Policy

[i] The Academy Advisors is the policy affiliate of The Health Management Academy, working with Leading Health Systems on policy analysis and development

[ii] The Health Management Academy provides executive education and advisory services to C-suite executives from integrated health systems across the United States. Our health systems membership can be found at http://www.hmacademy.com

Organization Name

The Brookings Institution- Engelberg Center for Health Care Reform

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Phone Number (202) 741-6567**.**

Please select the option that best describes you.

Part of a Medicare ACO

Part of a Commercial ACO

Part of both a Medicare ACO and a Commercial ACO

Not part of a Medicare ACO or a Commercial ACO

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

A. The Pioneer ACO Model was designed for health care organizations and providers that are already experienced in coordinating care for patients across care settings as well as engaging in outcomes based contracting. The Model is now entering its third performance year with 23 organizations. In addition to increasingly aggressive risk arrangements, CMS offers eligible Pioneer ACOs the opportunity to transition from fee-for-service (FFS) payments to monthly population-based payments to give these organizations more revenue flexibility in determining how to best motivate providers to improve quality of care and reduce costs for their patient populations. As more and more health care organizations begin to hone their skills in care coordination and engage in outcomes-based contracting, CMS is considering giving additional organizations the opportunity to become Pioneer ACOs. To that end, CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model?

Yes

No.

1A. Why or why not?

As the Pioneer pilot program continues, CMMI should incorporate its successful features in such areas as risk sharing into the "mainstream" MSSP program. The programs should remain aligned, with the Pioneer program helping to identify ways to enhance quality improvement and cost savings in the ACO program in traditional Medicare.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria?

Limit the number of selected organizations

Accept all organizations that meet the qualifying criteria.

2A. What are the advantages and/or disadvantages of either approach?

Refinements in the specification of qualifying criteria would enable CMMI to elicit a higher rate of successful applications and avoid applications from organizations that are not well suited to the goals of the Pioneer program. Clear criteria would also support feedback from stakeholders about ways in which the program could generate more successful applications.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

Especially as CMMI moves toward more risk-based models, reduced uncertainty about risk is critical. CMMI should take steps to enable participating organizations to be able to better understand how they are performing against the quality and cost benchmarks, reducing uncertainty and enabling participants to better target their quality improvement activities. For example, timely data sharing with clearer mapping between claims data feeds and subsequent quarterly and annual benchmark reports would substantially reduce uncertainty and enable improved performance. Refinements in how benchmarks are calculated to address factors like wage index changes would also make program performance more predictable. More predictable risk will enable more effective participation.

B. Population-Based Payments: CMS allows Pioneer ACOs to transition to population -based payments (PBP) that offer revenue flexibility to provide furnish services not currently paid for under Medicare fee-for-service (FFS), and to invest in care coordination infrastructure. In lieu of explicit requirements that Pioneer ACOs maintain adequate financial reserves to pay the claims of their participant Pioneer providers/suppliers, CMS currently requires Pioneer ACOs to demonstrate a specified level of savings in previous performance years to become eligible for PBPs. Selection of PBPs does not affect the risk profile of the Pioneer ACO's payment arrangement.

Eligible Pioneer ACOs may elect to receive PBPs that represent a selected percentage (e.g., 40%) percent) of their expected Medicare Part A and Part B FFS revenues or their expected Part B FFS revenues, based on historical claims of participating Pioneer providers/suppliers that agree to accept reduced FFS payments. (The current PBP policy does not allow for ACOs to request a different reduction amount on Part A and Part B services, and does not affect the payments of non-Pioneer

providers/suppliers caring for the Pioneer ACO's aligned beneficiaries) In turn, participating Pioneer providers/suppliers will receive FFS payments on submitted and payable claims for the services furnished to aligned Pioneer beneficiaries, reduced by the same selected percentage (that is, selection of PBPs representing 40% of expected Pioneer ACO revenues would be coupled with a 40% reduction in FFS reimbursements to participating Pioneer providers/suppliers for services furnished to aligned Pioneer beneficiaries). CMS does not currently allow suppliers of durable medical equipment to be included on the list of Pioneer providers/suppliers to receive reduced FFS payments upon which the amount of PBPs paid to the ACO is based. At the end of the year, CMS will include the amount paid to the Pioneer ACO in PBPs and the amount by which FFS payments to participating Pioneer providers/suppliers were reduced as part of the financial settlement of shared savings/shared losses.

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant importance when deciding to participate in the PBP?

Yes

No.

1A. Why or why not?

Given the different abilities of ACOs to transition to PBPs, choosing different FFS reductions would enable a broader range of organization to transition to complete PBPs, and would enable CMMI to learn more about the best ways to support provider transitions to bearing more risk.

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments?

Yes

No.

2A. Why or why not?

Inclusion of DME suppliers and other types of providers provides more avenues for ACOs to support improvements in care, but this should be a contractual issue between DME suppliers and ACOs.

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves?

Yes

No.

3A. Why or why not?

Demonstrated ability to meet cost and performance benchmarks are important considerations for ACO success and sustainability, as are financial reserves or reinsurance arrangements especially for smaller or less experienced ACOs that are ready to take on substantial financial risk. All should be considered in ACO program requirements.

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

Yes

No.

4A. Why or why not?

As noted above, moving the Pioneer program toward greater financial and performance accountability will be easier to the extent that these performance risks are predictable for the participating organizations. Any steps that can improve predictability (e.g. greater clarity of how claims data feeds relate to subsequent CMS performance calculations against benchmarks) will enhance effective participation and help ACOs focus on the best opportunities to improve care.

Section II: Evolution of the ACO Model

The Innovation Center intends to continue testing new approaches of accountable care to support the future refinement of the Shared Savings Program and/or to lay the foundation for other CMS ACO initiatives with three major goals:

• Increase integration of total Medicare and Medicaid expenditures and populations in accountability models;

• Give providers more tools and resources to improve care outcomes and efficiency; and

• Continue to preserve beneficiary freedom of choice in FFS Medicare.

CMS is seeking input on models that (1) transition ACOs to full insurance risk, (2) hold ACOs accountable for total Medicare expenditures (Parts A, B, and D), (3) integrate accountability for Medicaid outcomes, and/or (4) offer ACOs payment arrangements with multiple accountability components (such as shared savings/losses, episode-based payments, and/or care management fees). CMS recognizes that these strategies are not necessarily mutually exclusive, such that a new initiative could incorporate several of these strategies. CMS also believes that the adoption of the ACO model by private payers offers an opportunity to strengthen the incentives in the model while reducing burdens on providers and is interested in opportunities to advance that alignment.

A. Transition to greater insurance risk – ACOs assuming full insurance risk would face issues similar to current organizations participating in the Medicare Advantage program. At the same time they would encounter unique challenges because beneficiaries would retain their traditional Medicare benefits

and freedom to select providers and services of their choice. The questions that follow attempt to better understand these issues. .

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations?

Yes

No.

1A. What are the potential benefits and risks to the Medicare program and beneficiaries?

This would provide incentives for ACOs to focus on person- and population-level outcomes and costs. One concern is that the "higher-powered" incentives may encourage restrictions on needed care or efforts to select favorable-risk patients.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

ACOs at full insurance risk should be responsible for Medicare Parts A, B, and D.

3. Are there services that should be carved out of ACO capitation? Why?

CMMI must focus on creating a feasible pathway for ACOs to transition to limited and partial capitation, and potentially to full capitation. These intermediate steps should consider carveouts of certain types of services or costs. Private-sector ACO arrangements provide growing evidence on practical partial-risk models.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

A range of agreements between ACOs and Medicare providers and suppliers other than physicians and hospitals (e.g., post-acute providers, product manufacturers) would improve the ACOs ability to manage full risk.

5. What key elements of the regulatory and compliance framework for Medicare Advantage should be adopted for ACOs assuming full insurance risk? What regulatory and compliance elements in Medicare Advantage would NOT be appropriate for ACOs assuming full insurance risk?

Medicare Advantage has important lessons for ACOs, but CMMI needs to provide a pathway with intermediate steps for ACOs to transition to full insurance risk – indeed, many risk-bearing provider organizations are or are aiming to become Medicare Advantage plans. The Medicare Advantage and full-risk ACO programs should be aligned; however, ACOs have different considerations than Medicare Advantage plans, especially when they are bearing less than full risk.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

State insurance regulations are significant features and important costs for full-risk health care organizations. The experience of integrated health care delivery systems and Medicare Advantage can provide insights for ACOs on meeting necessary requirements, which CMMI should consider as it is developing models for ACOs to transition toward bearing greater risk. ACOs may also be able to comply with state requirements by partnering with traditional health plans, and CMMI should encourage the exploration of such approaches.

What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services.

7. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

A well-developed pathway toward taking greater insurance risk should be developed, with significant opportunity for stakeholder input; this pathway should clarify expectations about the necessary infrastructure.

The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking.

8. What are approaches for setting appropriate capitation rates?

CMS has extensive experience with setting capitation rates (i.e. Medicare Advantage) that will be helpful. Any capitation rates in the ACO program should not be misaligned with Medicare Advantage rates in a manner that would encourage participating in one program versus the other for financial reasons, i.e., reasons other than the most effective way to deliver care for beneficiaries.

8A. What are the advantages and disadvantages of using national expenditure growth trends?

8B. What about for using a local reference expenditure growth trend instead?

9. What are the advantages or disadvantages of different strategies for risk-adjustment?

> **(Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)**

As noted above, while different strategies have different strengths and weaknesses, whatever approach is used should avoid significant mis-alignment between Medicare Advantage plans and capitated ACOs.

10. What benefit enhancements (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes?

In conjunction with a continued emphasis on meaningful quality measurement and improvement, CMMI should facilitate the ability of ACOs to offer reduced co-pay and premium discounts to beneficiaries for lower-cost services within the ACO network. In conjunction with accepting these opportunities for cost saving, CMMI could also evaluate giving beneficiaries could the option of accepting higher co-pays when they select providers outside the ACO – even with such higher non-ACO copays, their overall out-of-pocket payments would still be lower. Exploring such options for enabling beneficiaries to share in the savings of better care arrangements should be a high priority for the Pioneer program.

10A. How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

A range of benefit enhancements should be considered, given the differences in benefit design and the nature of services across these programs.

11. What are potential program integrity issues that ACOs transitioning to full insurance risk may encounter and what are appropriate preventative safeguards?

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection?

The Medicare Advantage program provides extensive experience on marketing regulation that may be relevant for further steps toward beneficiary engagement in ACOs. However, especially since many ACOs are likely to remain partial-risk or shared-savings, and since Medicare beneficiaries in ACOs are likely to continue to have coverage outside of the ACOs (albeit with higher copays), adverse selection issues may be less of a concern than other factors affecting feasibility of implementation in the near future.

> **Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries.**

13. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology?

Yes

No.

13A. What are advantages/disadvantages of allowing beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

Voluntary alignment would better engage patients and make them more likely to partner with ACO providers to get quality care at a lower cost.

B. Integrating accountability for Medicare Part D Expenditures – An approach for increasing Medicare accountability is for ACOs to integrate Part D expenditures as part of their approach to care delivery and health care transformation. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes.

1. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements?

Pharmacy services can have a major role in generating savings and improving quality. Increased integration or inclusion of Part D holds the potential to address some obstacles currently facing ACOs in their efforts to align with pharmacies, PBMs, and pharmaceutical manufacturers to improve care. Inclusion of Part D data for ACOs would also be extremely helpful in identifying opportunities for quality improvement and thus reducing uncertainty about improving performance in the program (for ACOs today, data is currently not available in real-time and is difficult to use in order to adequately influence patient behavior without a pharmacy benefit manager). Partnerships involving patient data sharing raise privacy and other concerns that should be addressed, but this should not prevent CMMI from developing opportunities for coordination to improve care by ACOs and groups involved in Part D services.

1A. What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies?

Yes

No.

2A. Why or why not?

There is large opportunity for savings and quality improvement by including Part D, but many are not currently prepared for a transition to full risk. Thus, transitional and partial risk-sharing models should be considered by CMMI and further vetted with stakeholders.

2B. If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current

Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

As ACOs move to accountability for Part D expenditures, they will need to consider their ability to comply with insurance licensure and solvency requirements, something that they generally do not have experience with to date. As noted above, partial risk models should provide transitional paths for ACOs.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures?

Yes

No.

3A. What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

Pathways to accountability starting with shared savings and partial risk would help. For example, ACOs could have Part D upside risk (or could work with Part D plans to provide additional support in return for participating in Part A/B shared savings) in the first year followed by fuller risk arrangements in subsequent years, thereby creating a pathway for increasing risk. CMS should also provide Part D data to help target interventions.

C. Integrating accountability for Medicaid Care Outcomes – As part of the State Innovations Model CMS is working with States to tailor payment reforms that reflect health care priorities identified by States and local stakeholders. CMS seeks input on approaches for ACOs to assume increasing accountability for Medicaid outcomes. .

CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations.

1. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

Yes

No.

1A. Why or why not?

Accountability for Medicaid outcomes in addition to Medicare outcomes will depend on the ACO's capacity for addressing the additional beneficiary needs and services that differ in Medicaid. Thus, CMMI should develop evidence on a transition path for ACOs toward Medicaid accountability. Since this will introduce additional uncertainty for ACOs, CMMI should take additional steps to reduce it, such as ensuring that timely Medicaid data feeds and clear Medicaid performance benchmarks are developed. ACO options to support integration of behavioral, social, and other community services for Medicaid beneficiaries should be developed.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes?

(For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries ? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?)

Integrating accountability for Medicare-Medicaid beneficiaries should be a high priority for CMMI, since dual-eligible beneficiaries present many opportunities for improved care coordination. For example, more effective use of long-term services and supports covered by Medicaid could reduce complications leading to greater acute-care use covered by Medicaid. This could also help ACOs better manage care for dual-eligibles already participating in the ACO. For such models to succeed, it will be essential for CMMI to implement a truly integrated financing model, one in which *overall* Medicare/Medicaid savings can be shared across the Medicare and Medicaid programs. For example, a well-designed Medicare-Medicaid ACO program would enable increased spending on long-term services and support (leading to higher Medicaid spending) to be offset by larger savings from fewer acute-care complications (leading to overall savings that is more than sufficient to offset any additional Medicaid spending).

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system?

States can play an integral part in promoting accountable care arrangements, particularly for Medicaid populations. Whether through waiver processes or pilots, states can provide opportunities and incentives for providers and payers to continue innovating on novel payment and delivery approaches that control costs and improve quality which maximize alignment with and programmatic frameworks developed from existing programs such as the Pioneer ACO model. A number of states have launched regional-based accountable care collaborative that are already yielding positive results. CMMI should encourage states to develop these new payment delivery systems and allow necessary flexibility to foster innovative efforts. CMMI could support these efforts by developing and implementing consistent and meaningful performance measures for Medicaid beneficiaries, and consistent methods for data sharing and benchmark calculation. States can also use their regulatory, purchasing, and convening powers to promote multi-payer and system-wide alignment, and CMMI should consider ways to support states that seek to do so.

3A. What roles should States play in supporting model design and implementation?

3B. Do States have adequate resources to support an ACO initiative in collaboration with CMS?

While a number of states have succeeded at innovative ACO-type arrangements, states would benefit from additional collaboration and support from CMS. Successful state efforts will not only benefit individual states, but produce evidence with implications for Federal spending and quality of care in other states.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting?

While all ACOs are attempting to use Medicare FFS data to drive care improvement and performance reporting, many continue to experience challenges in using data from CMS, and in understanding what these data ultimately mean for their performance measures relative to benchmarks. This uncertainty should be reduced to help the ACO initiatives succeed. The gaps limit the ability of ACOs to take timely, effective steps to improve care and lower costs. These challenges and uncertainties may be compounded when Medicaid is included unless they are addressed proactively. CMS should promote greater alignment between the two programs in quality measures, benchmarks, and data sharing to help ACO providers improve care.

4A. What are the capabilities of providers in integrating this data with electronic health records?

4B. What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures?

(Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?)

D. Other Approaches for Increasing Accountability – CMS seeks input on other potential accountable care models not specifically addressed in Approaches A through C.

A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns.

1. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries?

There is considerable promise in geographically-based ACO models; however, experience with such models is limited. In general, current ACOs are not ready to consider accountability for all beneficiaries residing in their service area. Developing effective geographically-based models should be a priority for CMMI but will likely require significant partnerships with local and possibly state governments, as well as advanced payment from CMS or other sources to support investments in the appropriate infrastructure (e.g. compatible information technology, local coordination and governance activities, addressing antitrust concerns). A transition path starting with limited geographic accountability would also likely be helpful. It is important to consider that certain geographic areas may be better-suited for developing such models (e.g., depending on other regional payment and delivery reform efforts underway). How to implement benefit enhancements to engage beneficiaries in these community-based efforts should also be considered. In addition, it would be critical to consider how the savings would be

shared among health care providers and others participating in the geographically-based quality improvement efforts (e.g., community and public health organizations) in order to ensure shared incentives and alignment on care coordination approaches.

1A. What are the most critical design features of a provider-led community ACO model and why?

1B. What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area?

1C. Are there models to consider that better integrate community-based services beyond the traditional medical system?

In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives.

2. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined?

Yes

No

2A. More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments?

Yes

No.

2B. If so, what would the most critical features of such a "layered" ACO be and why?

Payment reforms to support better care and lower costs for primary-care providers and specialists, such as medical home initiatives and bundled payments, can and should reinforce population-level ACO payment reforms. CMS should focus on aligning performance measures and improved data sharing across these programs, as well as on methods for calculating and distributing total shared savings. Many private payers are currently using medical home models to transition into physician-led ACOs, and are combining payment reforms like bundles and other case-based payments with ACO reforms, because they are reinforcing.

E. Multi-Payer ACOs – CMS has required that Pioneer ACOs demonstrate experience with risk-based contracts as a pre-condition for assuming such contracts with CMS as well as to encourage multi-payer alignment of incentives. CMS is seeking input on how best to promote multi-payer alignment of payment incentives and quality measurement. .

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

CMS could enhance its efforts to support the development and implementation of consistent performance measures that are acceptable to private payers as well, and could also seek to promulgate best practices for sharing claims and other relevant payer data and for calculating benchmarks. As noted above, these steps are important for reducing uncertainty in the ACO program anyway. As we have noted elsewhere (for example, in our "Bending the Curve" report), more clarity in the regulatory environment involving DOJ and FTC, with a greater focus on performance results, would also be helpful.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden?

Alignment across payers on meaningful quality measures that increasingly focus on outcomes and patient experience would be very helpful for providers seeking to improve care throughout their practices. Instead of relying on measures that CMS and other payers calculate after the fact, a shift to rely increasingly on measures that are generated from data available to ACOs at the time of care or as near to the time of care as possible (e.g., timely and consistent claims data feeds) would help both improve performance and reduce burdens on ACOs. There are a number of important steps that CMS could take now to support this transition (e.g., further development of standard methods and reliable systems for providers to report on performance measures electronically).

February 28, 2014

Centers for Medicare and Medicaid Services
Center for Medicare and Medicaid Innovation

To Whom It May Concern:

The SCAN Foundation welcomes the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) Request for Information: Evolution of ACO Initiatives. The SCAN Foundation is dedicated to advancing a coordinated and easily navigated system of high-quality services for older adults that preserve dignity and independence. The ideal system of care would consist of medical providers who are knowledgeable about long-term services and supports (LTSS) partnering with community-based organizations (CBOs) to coordinate care (primary, behavioral, LTSS, etc.). The Accountable Care Organization (ACO) is one model for achieving this goal. We commend CMS for continued support of integrated care. Our comments below, center on Section II, Parts C, D, and E of the Request for Information.

ACO Accountability for Medicaid Outcomes (Section II, Part C, Question 1)

People with multiple chronic conditions and functional limitations eligible for Medicare and Medicaid often face a fragmented system of care with siloed funding sources. In a fee-for-service environment, no payer is singularly responsible for coordinating care or managing overall costs of care, which can result in limited access, duplication of services, and use of more costly care. Integrating funding streams can allow for investment in services and providers that more effectively and efficiently coordinate and deliver care. Therefore, we strongly encourage CMS to consider allowing ACOs that focus on Medicare outcomes to specialize in the population dually eligible for Medicare and Medicaid. This will provide ACOs with the maximal flexibility to access the full range of benefits (both medical and supportive) that a beneficiary might need.

Role of States in Incentivizing Development of Integrated Care Systems (Section II, Part C, Question 3)

States have a critical role to play in ensuring the funding and quality of services delivered within their Medicaid program, including home and community-based services. Already, states engage in different models of integration; selected states are already participating in the Financial Alignment Initiative, in which states and CMS partner to integrate the financing and provision of services for those dually eligible for Medicare and Medicaid. Some states are pursuing integration under this initiative through managed care vehicles while others are looking at health homes in a fee-for-service model to integrate care. The ACA requires that health plans offering a D-SNP, which is another model of integration for

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dually eligible beneficiaries, must contract with the state going forward for the Medicaid component of the D-SNP, which creates an important opportunity for states not engaged in the Financial Alignment Initiative to begin to work on issues of integration in a more meaningful way. Minnesota is employing D-SNPs in its own demonstration to better integrate care. This is an important role for states to play and in some cases (i.e., with D-SNPs), it is mandated going forward that they engage on these issues. The ACO is yet another model that states can and should consider supporting as a vehicle for building integrated care systems.

States can play several key roles in supporting integrated care systems. Most directly, states can contract with ACOs for Medicaid services, allowing them to broaden their coverage and provide for the fuller array of medical and supportive services. States can convene both medical and supportive services providers so that these professionals may better understand how the other works and foster contractual relationships that can lead to better care integration at the ACO level.

Reporting of Quality Measures (Section II, Part E, Question 2)

Measuring quality of integrated care in ACOs will require the development of new metrics focused on the person's needs and preferences, particularly in the areas of functional and behavioral health needs, in addition to traditional clinical measures. A uniform assessment identifying the individual's health and functional needs and preferences is critical to developing a care plan that may lead to better quality of care and quality of life. Furthermore, an integrated data infrastructure (HIT) is a critical element to ensuring that assessment and other clinical information can be shared across provider settings for care planning and care delivery purposes. Establishing the information architecture and ensuring that all providers access and use it reduces duplication of services but also reduces duplication of data collection for quality measurement and reporting purposes. This is critical to creating metrics that meaningfully describe the process and outcomes of integrated models and reporting them in a way that is least burdensome to providers.

Thank you for the opportunity to express the importance of comprehensive care coordination and LTSS in the development of ACOs addressing the needs of older adults and people with disabilities receiving services through Medicare and Medicaid. Ensuring the individual is at the center of the process and the proper infrastructure is created to support care coordination is vital to the success of ACOs.

Sincerely,

Bruce A. Chernof, M.D.

President and CEO

VERMONT

State Innovation Model

109 State Street
Montpelier, VT 05609
www.gmcboard.vermont.gov/sim_grant

March 1, 2014

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard, Baltimore, MD 21244

Dear Ms. Tavenner:

The Centers for Medicare and Medicaid Services (CMS) have asked for input from various parties regarding the evolution of CMS Accountable Care Organization (ACO) initiatives. The State of Vermont appreciates the opportunity to respond to this request. Given the general nature of our comments, we chose to submit them through this letter rather than through the very specific format of your RFI. Our ACOs are submitting more detailed comments through the website.

Governor Shumlin has advanced a multi-year reform agenda that includes:

- Cost control and evaluation of system performance through our Green Mountain Care Board;
- Changes in payment and delivery across all payers to reward efficiency and population health improvement and move risk, in a thoughtful way, from payers to providers;
- Major investments in a statewide system of health information exchange that promotes efficiency and quality; and, very importantly,
- A move away from employer-based health insurance and toward a unified, universal, tax-based financing system for health insurance in Vermont.

ACOs are an important component of Vermont's health care delivery and payment reforms and play a key role in our State Innovation Model (SIM) Testing Grant. The Governor believes payment and delivery system reform are essential precursors to guaranteeing that all Vermonters are covered through a universal and fair health care financing system. ACOs can be an important part of organizing Vermont's providers to be accountable for health care costs and quality.

Vermont's ACOs are unique in two respects:

- Combined, our three ACOs include almost all providers in the state; and
- All of our major payers have a functioning program for sharing savings with those ACOs – the SIM grant supports the expansion of a Shared Savings Program to Medicaid and commercial insurers.

To date our ACOs have been extremely supportive of Vermont's efforts to develop Medicaid and commercial shared savings programs, which started with the Medicare Shared Savings Program as a foundation. The ACOs have helped shape the payment methodologies and quality measures to be used in both. Vermont would like to see the Medicare ACO programs continue to evolve to provide a leading edge, in terms of payment, risk allocation and quality measurement methodologies, for our statewide, all-payer efforts. Specifically, we are hoping to see our ACOs move to population-based payments for a preponderance of their attributed lives by 2016. Medicare participation in this evolution will be essential to our success. It also is essential that the ACO model allow for alignment of incentives across beneficiaries, providers (both acute and long-term care) and all payers.

Our answers to your questions about ACO program evolution largely echo those of our ACOs. We have reviewed detailed answers from Dartmouth-Hitchcock Medical Center (a Pioneer ACO) and OneCare Vermont (a statewide ACO in Vermont participating in Medicare, Medicaid and commercial shared savings programs) and generally support their suggestions. Our summary of state-supported input is:

- Allow ACOs to take more risk and gain more reward. Specifically, develop a hybrid approach, between the Medicare Advantage program and traditional fee-for-service, that does not place all of the responsibilities of a Medicare Advantage Plan on ACOs at this time. Our primary goal for ACOs should be that they are great delivery systems, and not insurance companies;
- Allow nurse practitioners and physician assistants to be considered PCPs;
- Simplify the economic model embedded in the ACO programs to provide strong and clear incentives for delivery system redesign;
- Provide reliable and timely data to ACOs to help them manage risk and quality;
- Reward networks that increase their scope and provider participation over time;
- Create an alternative financial model for those ACOs ready to assume more risk, with appropriate risk-mitigation strategies that would include provision of reinsurance (purchased by the ACOs), or withholds;
- Encourage ACOs to take risk for services beyond Medicare A and B. Ultimately, integration of prescription drugs, long term services and supports, mental health and preventive care in ACO financial models is essential to making them "population health management" organizations;
- Provide leadership on developing the methodology for both payment and quality measurement for evolving ACO programs, as other payers will work from that point;
- Allow for creative approaches to ACO program design in states like Vermont where we can show both statewide provider participation and meaningful state oversight.

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State Innovation Model

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Thank you again for the opportunity to offer our input. We are happy to answer any further questions you might have.

Sincerely,

Anya Rader Wallack, Ph.D.
Chair
Vermont State Innovation Model project

Robin Lunge
Director of Health Care Reform

cc: Governor Peter Shumlin
Al Gobeille, Chair, Green Mountain Care Board

SECTION I: Additional Applicants to the Pioneer ACO Model and Feedback on Current Model Design Parameters

CMS seeks input on the level of interest in the field for CMS to open a second Request for Applications for the Pioneer ACO Model.

1. Would additional health care organizations be interested in applying to the Pioneer ACO Model? Why or why not?
   Organizations not currently Pioneers but that have been successful as SSP ACOs likely would have interest in becoming a Pioneer because some of the model differences would likely be seen as more favorable. In particular, the 1% fixed MSR, opportunity for greater than 50% risk sharing, and prospectively determined attributed population might be preferred. The ability to have Nurse Practitioners considered as PCPs also would be attractive to some organizations. The biggest deterrent to new Pioneer applications would be the magnitude of downside risk relative to the model's economic complexity and developmental instability, current inability to provide Pioneers with "sub-ACO Benchmark targets" for distinct geographic participants in the ACO, and the current lack of closer to real time provision of performance measures that could afford an ACO adequate notice to take corrective action within a performance year.

2. If additional applicants were solicited for the Pioneer ACO model, should CMS limit the number of selected organizations or accept all organizations that meet the qualifying criteria? What are the advantages and/or disadvantages of either approach?
   The primary reason to limit Pioneer acceptance is to preserve the high level of support that CMMI has been able to afford the Pioneers to date. If accepting all qualifying ACOs would lead to a reduced service level then limits should be set.

3. Other than the options for refining population-based payments outlined in Section B below, should any additional refinements be made to the Pioneer ACO Model that would increase the number of applicants to the Pioneer ACO model?

The biggest refinement that would provide greater comfort for ACOs to seek Pioneer status would be to provide for greater beneficiary "skin in the game" to manage total cost of care. Allowing unfettered access to services anywhere regardless of ACO endorsement of the service need or appropriateness is concerning to providers taking two-way risk. Other refinements that would help attract ACOs include:

-providing full access to claims data including Substance Abuse and Behavioral Health data
-eliminating the data sharing opt out provision; or if unable to eliminate this provision, then exclude any beneficiary opting out of data sharing from the ACO risk population
-allowing members to "attest into" an ACO
-improving the Risk Adjustment perhaps using the Medicare Advantage approach but certainly eliminating the matched cohort approach that is not understandable and may not sufficiently risk adjust over time.

Lastly, some Pioneer ACOs have significantly expanded their ACO participant rosters beyond the core group of providers included in the initial Pioneer model application in 2011. Many did this

to increase the geographic reach of the Pioneer model in their respective market places. However, the current Pioneer ACO baseline benchmark methodology was designed based on the premise that the initial core provider roster identified at the beginning of the three-year agreement period remained static except for routine hires and terminations, but did not contemplate additions of entire health systems or large physician group practices to the ACO over that three-year time period. The model will have to be refined to accommodate these type of provider expansions in order to achieve the goal of achieving the Triple Aim more and piloting these type of advanced payment models more broadly.

Population-Based Payments:

1. Would being able to choose different FFS reduction amounts for Part A and Part B services be of significant import when deciding to participate in the PBP? Why or why not?

YES.

Given the variability of in most Pioneers and MSSPs participant construction, PBP should be flexible enough so that they reflect the relative proportion of overall *participant* payments for attributed beneficiaries accounted for by Part A versus Part B payments. So for example, a more 'facility' based ACO could request that a higher proportion of Part A based payment be considered for their PBP than a multi-specialty physician based ACO might. We recommend that there be enough flexibility in the model so that these proportions can be modified by individual ACOs to reflect their willingness and ability to take more risk. For example, a multi-specialty physician based ACO that has been very successful in managing hospital-based utilization could ask for a high % PBP.

However, our overall recommendation is that an alternative model rather than alterations in the current PBP model is more appropriate (see responses to **transition to greater insurance risk** questions).

2. Should CMS allow suppliers of DME equipment to be included on the list of participating Pioneer providers/suppliers that will receive reduced FFS payments? Why or why not?

YES.

As a general principle, ACOs should be encouraged to extend their participants to include providers of any services/supplies that are deemed important for delivering on the triple aim. These would include DME suppliers, but could also include retail pharmacies, hospice providers, etc. Current ACOs lack scope and resources for managing chronic illness and helping patients with chronic illness navigate effectively and efficiently through the healthcare system. Incorporating the best aspects of the current ACO models while selectively reaching into the acute care sector and out to community providers will result in true patient-centered, coordinated care. The goal is to move towards the development of a *medical neighborhood* model. This would require ACOs to incorporate additional providers into the patient-centered team, including medical and surgical specialists (specialty providers, many of whom are not currently participants), clinical pharmacists, palliative care providers, behavioral health providers, DME

providers, and community organizations. These new models recognize that longitudinal care requires shared accountability across a variety of settings. These relationships need to be supported by payment models that support and incentivize these providers. Therefore, risk based contracts should allow flexibility for a wide variety of relationships among suppliers. In addition to extending PBP payment models to these providers, CMMI should allow ACOs to enter into gain sharing models with these participants, as is allowed in the BPCI).

3. Should CMS reconsider the requirement that a Pioneer ACO generate a specified level of savings in previous years in order to be eligible to elect to receive PBPs, and instead establish clear requirements for financial reserves? Why or why not?

YES.

The shared savings payment models under which Pioneer currently operates has required a "leap of faith," promising that investments and ongoing operational costs designed to address over- and under-use *now* will result in improvements in the health of the population and a return on investment in the *future* when the final reconciliation process has been completed. This challenge is amplified by fact that these programs are for attributed Medicare beneficiaries only (see below). These circumstances have resulted in a "tragedy of the commons" wherein systems operate under the volume-based reimbursement model and address obvious and easier clinical opportunities that require minimal investment, but do not fully engage in those interventions likely to significantly reduce utilization and cash flow and/or require a full transformation in how clinical care is delivered.

'Failure' to generate a specified level of savings in previous years is confounded by the transition payment model that shared savings reflect. Therefore, we recommend that CMMI create an alternative model for those ready to assume more risk. However, it is not given that this should be based solely on financial reserves, in fact we recommend other risk-mitigation strategies that would include provision of reinsurance (purchased by the ACOs), withholds, and others (see below).

4. Should any additional refinements be made to the current Pioneer ACO PBP policy?

NO.

Transition to greater insurance risk

1. Should CMS offer ACOs capitation with insurance risk, similar to Medicare Advantage organizations? What are the potential benefits and risks to the Medicare program and beneficiaries?

YES (with modifications from Medicare Advantage).

In order to move the ACO effort forward, and to answer the question 'what happens after shared savings ends', will require creative effort on the part of CMS and providers. Many providers are ready and willing to participate in risk based efforts with CMS for both Medicare and Medicaid beneficiaries. However, we do not support the extension of the Medicare Advantage (MA)

program as the preferred model. Rather, we would like CMS to consider a hybrid model where CMS and interested ACOs develop a partnership that leverages their unique capabilities to develop a prospective, risk-based, capitated payments for attributed Medicare FFS, Dual, CHIP, and Medicaid populations (see responses below to recommended modifications to the current attribution models).

This would entail that CMS continues to perform many of the typical 'member services' that an MA plan would do as CMS currently does: enrollment, claims processing, network development, eligibility assessment, etc. The ACO would be responsible for creating the local extended 'network' required under more progressive risk models. This would require them to extend the participants to other providers not currently considered as participants (e.g. DME, retails pharmacies, etc.); to create the gain sharing models *within* the ACO for the current and added participants, distribute gains/collect losses, etc. It also will require the ACO to add additional member services to increase 'loyalty', promote health, etc.

We propose that CMS maintains the infrastructure, roles, and processes needed to implement the prospective, risk-based, capitated payments for attributed Medicare FFS and Duals. The prospective payment would be based on historical payments to ACO participants, with a 'withhold' for historic out of ACO payments. Participants would submit bills as they would under FFS, however, CMS would use a $0.00 payments claim adjudication methodology for submitted claims for ACO participating providers. Prospective payments would address both the cash flow impact of successful care coordination services AND act as a change management lever to support and alter FFS 'behavior' that is a drawback of the current Pioneer and MSSP programs. Further, the prospective payments will be used by the systems to invest in infrastructure and personnel to implement new care models and new provider compensation models. Non-ACO participant providers will be paid by CMS under usual FFS Medicare.

We would recommend that CMS require the ACO participants to submit claims allowing CMS and the providers to assess and value the volume and types of care being delivered under these new models; allowing CMS to reduce the risk of the ACOs withholding valued services to beneficiaries, and both CMS and the ACOs to measure total services and monitor some of the quality metrics.

CMS should consider several strategies to mitigate the risk of the ACOs being unable to re-pay CMS should costs grow at a rate greater than the targeted growth. For example, CMS could require a pre-specified amount of the prospective payment be held in escrow by the systems as reserves in case the system needs to repay CMS (if the global budget target is exceeded); CMS could require reinsurance be purchased (ideally, CMS could act as the reinsurer), etc.

Consistent with the hybrid approach, we would encourage CMS to develop an ACO beneficiary benefit design that can continue to allow for freedom of choice but would have some differential beneficiary cost sharing if that member opted to receive elements of care from a non-ACO Participant for a service that was included in the payment bundle or capitation responsibility of the ACO.

See further detail below.

2. What categories of spending should ACOs at full insurance risk be responsible for? (For example: Medicare Parts A and B, Medicare Parts A, B, and D, or Medicare Parts A, B, and D and Medicaid for Medicare-Medicaid beneficiaries)

We believe that the ACOs should be at risk for Medicare and Medicare-Medicaid A, B, and D; we recommend that some services be carved out (see below).

3. Are there services that should be carved out of ACO capitation? Why?

YES.

The ACOs should be primarily at risk for medical services only. This encompasses the majority of services paid for by Medicare. However, to the extent that the Medicare-Medicaid beneficiaries (Duals) and Medicaid enrollees (see below) are included, services such as Long Term Support Services (LTSS), transportation, and other types of custodial or non-medical services should be carved out from the risk contracts.

4. What type of agreements with non-ACO providers would the ACO need to adopt to take on full insurance risk for a beneficiary population?

ACOs at full insurance risk will need the flexibility to make a variety of arrangements with non-ACO providers (as allowed in BPCI). As noted above, at a minimum ACOs will need the latitude (and regulatory relief) to enter into gain sharing relationships with entities such as home health and hospice agencies, DME providers, retail pharmacists, and community based mental health providers.

Further, ACOs should be allowed to include non-traditional providers in the care team, covering their reimbursement from the prospective population-based payments. For example, as the care team extends to include community based service providers, the ACO should be able to contract with them and use the risk based payments from CMS to reimburse them.

6. What challenges would ACOs encounter in meeting state licensure requirements for risk-bearing entities? What types of waivers to current regulations and/or fraud and abuse laws, if any, would be necessary for ACOs to take on full insurance risk for a beneficiary population?

In NH currently providers in risk contracting are not subject to state licensure requirements for risk bearing entities. However, the growth of ACOs and risk bearing contracts had led the state Department of Insurance to begin considering what, if any, requirements should be developed. As a federal program, we would prefer these requirements be largely established by the federal government and that Pioneers be provided with a waiver opportunity to avoid added cost of state compliance. In particular, if a State adopted a substantial bonding requirement for a risk bearing entity that would certainly be a big negative influencer for greater ACO Participation.

CMS needs to recognize that many ACOs function in relatively rural areas where few providers exist. Thus, some ongoing anti-trust waiver will be needed to permit these rural providers to collaborate effectively around ACO and Triple Aim goals.

ACOs will request that they receive waivers to several regulations and fraud and abuse laws if they are to enter into full (or partial) insurance risk models. These would likely include:

- 72-hour stays before referral to SNF
- Homebound criteria for home health services to be covered
- Requirement that ER patients be hospitalized before they can be transferred to a transitional care facility
- Requirement for an in-person physician visit within 30 days of in-home care
- Inability for nurse practitioners to authorize home care
- Anti-kickback Statue – CMS should support the extension of the 'safe harbor' regulations to allow gain sharing among providers who bear risk (even those who are not corporately part of the accountable system, as has already been addressed in the BPCI)
- Stark Law – Selective incentives for referrals to providers within the system should be allowed to foster integration
- Patient Choice Requirements – CMS should support the relaxation of the patient choice requirements to allow referrals to those entities that are part of the accountable system (for example home health)
- Quality Reporting- the Physician Quality Reporting System is focused on individual physicians and not system level care delivery. Meaningful Use standards force processes that may not help deliver and document the medical care needed. Hospital Quality Reporting continues to be focused on hospital care. The Annual changes in Reporting Requirements for each program (PRQS, MU, HVBP) does not provide the opportunity for systems to invest in processes that assure best outcome or in outcome measures that have defined, valid processes that assure best outcomes that are meaningful to beneficiaries. Ideally an ACO that keeps costs at historic levels but demonstrated a significant improvement in quality should be able to receive an economic reward within the payment model since the value of care would have been improved even though the cost of care alone did not decrease.

7. Medicare Advantage Organizations have significant infrastructure that ACOs do not currently have such as member services. What additional infrastructure would ACOs need to develop to be able to manage full insurance risk?

As noted above, we do not recommend that CMS follow the 'traditional' Medicare Advantage model as they consider insurance risk models. We recommend that Medicare maintain many of the functions that require infrastructure (enrollment, notification, claims processing, 'network management', etc.). However, we do recommend that ACOs contemplating risk-based models invest in information services infrastructure to increase the likelihood of success under these models. This infrastructure should focus on population segmentation, beneficiary outreach, care coordination, physician performance assessment, contract management, etc. ACOs will also need to develop, or contract for, expertise in such areas as actuarial services.

An additional area of investment ACOs will need is beneficiary 'engagement' strategies and operations. This will be particularly important in more competitive markets where beneficiaries

are more likely to receive care from non-ACO providers. In these markets, creating beneficiary 'loyalty' that results in greater within ACO utilization will be a key success factor (see below for additional comments on this issue).

8. What are approaches for setting appropriate capitation rates? The Pioneer ACO program currently uses a national expenditure growth trend for benchmarking. What are the advantages and disadvantages of using national expenditure growth trends? What about for using a local reference expenditure growth trend instead?

Ideally, CMS and its constituents would make an explicit decision about the total amount of health care services per capita it would purchase using a deliberative process. Recognizing that this is unlikely to occur in the foreseeable future, we recommend that CMS stay with a modified NATIONAL expenditure baseline. CMS should develop a method that allows those regions that are significantly below national averages in total expenditures to grow at a rate that is marginally above the national growth rate, conversely, those that are significantly above national averages in total expenditures to grow at a rate that is marginally lower the national growth rate.

We recommend strongly AGAINST a local reference expenditure growth trend. For both reasons of concern that a local growth rate target would lock in healthcare spending disparities AND for methodological reasons including regression to the mean advantaging high outliers and disadvantaging low outliers, instability in estimates, and most critically, the variance of performance within a region, we believe that a local growth rate target would be inappropriate.

9. What are the advantages or disadvantages of different strategies for risk-adjustment?
(Examples include demographic risk adjustment only and/or any of the Medicare Advantage risk adjustment methodologies.)

The current MA risk adjustment is fundamentally flawed. Specifically, the reliance on claims based diagnoses over adjusts for health status risk in high utilization/high spend providers and under adjusts for health status risk in low utilization/low cost providers. Evidence of this bias has been revealed in recent papers by the Dartmouth Institute faculty, assessment of the PGPD results and in the 'revenue optimization' venders who provide services to MA plans.

We strongly recommend that CMS uses an alternative risk adjustment process for ACO and other risk based contracts (including MA plans). Recent evidence suggests that a combination of demographic adjusters combined with self-reported health status information (e.g., smoking status, BMI, functional status) provides a much more defensible risk adjustment and avoids the bias inherent in all claims based methods. Further, such an approach also will provide the data needed to extend the patient experience and health outcomes measures that will become standard in all value based contracts.

10. What benefit *enhancements* (e.g. reducing co-pays for services delivered by ACO providers) would be appropriate for ACOs at full insurance risk to offer to their patients and how would these benefit enhancements improve care outcomes? How would benefit enhancements differ depending on integration across Medicare Parts A, B, D, and/or Medicaid?

Encouraging and incentivizing beneficiaries to stay within ACO participant providers is a key risk mitigation strategy for beneficiaries from an outcomes perspective and for the ACO from a

financial perspective. Given that more fundamental modifications to traditional Medicare benefits are unlikely, we recommend that CMS consider reductions of both co-pays and deductibles for Medicare beneficiaries who receive care from ACO participant providers. For those providers who have the capacity and capabilities, other enhancements to benefits, such as routine vision care, should also be allowed to encourage loyalty. Finally, as Medicare moves to prospective, risk-based, capitated payments other clinical interventions (e.g. group visits with health educators), integration with community health, etc. should be allowed and encouraged. Finally, the ACOs will need to be allowed to use these benefit enhancements in their beneficiary communications.

While waiving of copays and deductibles is not applicable, ACOs should be able to supplement benefits to Medicaid enrollees as well. For Medicaid this could include transportation (e.g. taxi vouchers), extending home health, etc. Allowing for home health coverage among ACO beneficiaries not meeting strict homebound criteria but who have a care plan promoting self care management with home health support should be considered.

PART D….not sure yet. We have little experience with this but our pilot program with CVS Silverscripts Plan D program has created a good partnership platform. Our understanding, however, is that CMS has not had a stable model/rules to risk share with CVS which then cascades down to our ACO arrangement. We would like the ability to direct market the Plan D ACO partners to our ACO beneficiaries since partnering on med management and compliance is critical for total cost of care not just the Rx cost portion.

12. What types of precautions should be taken by ACOs assuming full insurance risk to protect beneficiaries from potential marketing abuses limiting beneficiary freedom of choice? What are additional protections beyond those in Medicare Advantage that would be important for beneficiaries aligned to ACOs with full insurance risk to avoid adverse selection? CMS might invoke some type of "3 R" protection for full risk ACOs similar to what has been affected for the new insurance exchanges. Having more robust risk adjustment also helps protect against adverse selection.

The ACOs recognize that CMS needs to be vigilant regarding freedom of choice.
However, while CMS is concerned with abuses, the ACOs will ask CMS to modify their beneficiary communication and notification rules. The current MSSP and Pioneer models for beneficiary communication are cumbersome, bureaucratic and the approved communications are poorly designed. Further, if CMS is interested in ACOs managing prospective, risk-based, capitated payments the ACOs need to have some latitude on referrals to aligned providers. ACOs will need to work with CMS to balance these interests.

CMS should monitor the ACOs for their 'churn rate'. Based on a reference population, CMS could set upper thresholds for churn that if crossed would obligate trigger investigation.

13. Currently, beneficiaries are aligned to a Pioneer ACO through claims-based attribution. Pioneer ACOs are accountable for improved quality and lower expenditures for aligned beneficiaries. If Pioneer ACOs were at full insurance risk, should a beneficiary be allowed to elect alignment to a Pioneer ACO even if the beneficiary would not be aligned to the Pioneer ACO through the attribution methodology? What are advantages/disadvantages of allowing

beneficiaries to voluntarily align themselves to an ACO at full insurance risk rather than sole reliance on claims-based attribution?

YES. The benefits are primarily related to the ACOs' interest in loyalty, and the beneficiary's interest in high quality, value based providers. Further, to the extent that CMS allows, and the ACO offers, additional benefits, the beneficiary may be at lower risk for out of pocket expenses and have access to services that Medicare has not historically paid for.

The primary disadvantage is that this could potentially offer adverse selection: more healthy beneficiaries may be encouraged to voluntarily join. To avoid, or at least adjust for this possibility, CMS must choose a valid risk adjustment process.

Integrating accountability for Medicare Part D Expenditures

1. Current laws and regulations allow ACOs to establish business arrangements with Part D sponsors in order to align incentives in support of improving care coordination and outcomes. What factors, if any, pose barriers to the effectiveness of such collaborations? Are there any considerations, such as marketing considerations, that are relevant to the promotion of these business arrangements? What could CMS do in administering an ACO program to help ACOs and sponsors mitigate or avoid these barriers?

The primary barrier to better integration and risk sharing between ACOs and Part D carriers is that the market is highly disaggregated. Thus, if an ACO wanted to have these types of alignments, they would often need multiple relationships within a market. However, in some markets, ACOs will most likely wish to pursue participant relationships with one or more Part D providers and/or create a Part D plan of their own (with or without a partner).

CMS could greatly facilitate these relationships by requiring data sharing, encouraging appropriate gain sharing and marketing of specific plans (including through regulatory relief), and loosening the reserve requirements for those providers who want to create or sponsor their own Part D plan.

2. Would ACOs be interested in and prepared to accept insurance risk as Part D sponsors or through contracting with pharmacy benefits management companies? If ACOs assume accountability for Part D expenditures, what are the advantages/disadvantages of CMS requiring ACOs to be licensed under state law as a risk bearing entity and relying on the current Part D bidding process, versus creating a unified expenditure target for Part A, B, and D combined, with a unified risk adjustment method?

Yes, ACOs would be interested in accepting this insurance risk as medication management, reconciliation, and appropriate drug substitution are all big contributors to helping manage medical cost as well as prescription cost. We encourage CMS to create a unified expenditure target for Part A, B, and D combined. Such a target will a) reduce complexity; b) allow expected increases in Part D costs to be offset by likely resulting reductions in Part A and B costs

(particularly for targeted conditions such as mental health); and c) incentivize ACOs through total costs models to actually manage total costs.

3. Do ACOs currently have access to enough data to accept full risk for Part D expenditures? What other mechanisms would allow ACOs to assume accountability for Part D outcomes?

Maybe. CMS will need to improve Part D data capture (including those that arise through employer sponsored plans), and timeliness of the data transmission to ACOs. We are set up to receive this data now but CMS would need to ensure robust and timely submission. This could be accomplished by making this a requirement of Plan D providers. Our limited experience with one Plan D provider is that they have excellent data and willingness to support sharing if CMS rules can permit this.

Integrating accountability for Medicaid Care Outcomes

1. CMS has encouraged States to explore the use of integrated care models including ACOs for the care of Medicaid populations. Should ACOs caring for Medicare outcomes also assume accountability for Medicaid outcomes?

Qualified YES. ACOs are interested in increasing the total population 'under management' to include Medicaid populations. However, providers have had varied success in engaging and working with their state's Medicaid program. This variability is driven by local program designs, variation in reimbursement rates, and inabilities to honor contractual relationships on the part of the state (e.g., tax and match programs that become only tax programs).

We would look to CMS to support our engagement with the Medicaid program so that we can deliver high quality, effective, and efficient care for this disadvantaged population while at the same time not losing too much money. A major issue in this development is that some state Medicaid payments are so low that there is no opportunity to support any additional administrative costs to develop the many needed supports that a Medicaid population would have under a risk arrangement. Thus, for a Medicaid ACO to work effectively, there would have to be a minimum level of payment adequacy.

2. What populations should CMS prioritize in integrating accountability for Medicaid outcomes? For instance, should ACOs be accountable for outcomes among all Medicare-Medicaid beneficiaries treated by the ACO historically? Or, should the ACO be accountable only for those Medicare-Medicaid beneficiaries over 65 years old or under 65? Alternatively, should the ACO be accountable for outcomes of all Medicaid beneficiaries as well as CHIP beneficiaries? Should they be accountable for all those beneficiaries residing in a specified geographic area, regardless of whether they had been cared for by the ACO?

We recommend that all Medicaid populations be included, but not all services (e.g. LTSS as noted above). We recommend that CMS use an attribution model. This will require minimum eligibility for attribution. Therefore, not all enrollees of all programs will be eligible.

3. What should the role of States be in providing appropriate incentives to foster the development of an integrated care system? What roles should States play in supporting model design and

implementation? Do States have adequate resources to support an ACO initiative in collaboration with CMS?

Not surprisingly, capabilities and interests vary greatly across States. If ACOs are to take risk, the States will need to be active participants in the design, implementation, and operation of these programs. CMS should ensure that states make the necessary economic and operational support needed to legitimately support ACOs taking Medicaid risk. This would include having an adequate emergency mental health system to ensure acute care hospital and other medical costs are not incurred because of lack of state access/resources to the true psychiatric need of the ACO beneficiary.

4. What are the current capabilities of ACOs and other providers in integrating and using Medicare FFS and Medicaid FFS data to drive care improvement and performance reporting? What are the capabilities of providers in integrating this data with electronic health records? What are the capabilities of integrating information for care received in the community or from other non-traditional care providers?

Not surprisingly, capabilities will vary greatly across ACOs. We have invested in the technology and personnel to perform these data integration efforts. The Northern new England Accountable Care Collaborative (NNEACC), LLC is a shared services organization that currently supports 2 Pioneer and 2 MSSP entities. NNEACC integrates clinical data from laboratory, EHR, and HIE systems, claims from Medicare and commercial payers, and administrative data from a variety of sources. Once integrated, these data are augmented with predictive models and measures. This population health management information is presented to care coordinators, physicians and financial administrators through secure web-based workflow tools. CMMI could facilitate the development of NNEACC and other similar organizations through funding HIE and facilitating the scaling of common coding schemes.

5. What financial arrangements would be most appropriate for ACOs assuming risk for Medicare and Medicaid expenditures? Should CMS and States offer separate but coordinated shared savings arrangements to ACOs? Should CMS and States offer a unified shared savings arrangement that reflects combined Medicare and Medicaid expenditures?

While ideally this financial arrangement would be under one entity- presumably Medicare- given the tremendous variation in how states have implemented and operate their Medicaid programs, these will need to be separate. However, we do strongly encourage CMS and the States to coordinate their efforts with interested ACOs.

Other Approaches for Increasing Accountability

1. A provider-led community ACO would be an ACO that would be held accountable for total Medicare, Medicaid and CHIP expenditures, and quality outcomes, for all Medicare, Medicaid and CHIP beneficiaries residing in the ACO's service area, regardless of those beneficiaries' historical care patterns. What are options for accountable care models that are geared specifically for geographically aligned populations of beneficiaries? What are the most critical design features of

a provider-led community ACO model and why? What additional quality measures should be considered if an ACO is responsible for all covered lives in a geographic area? Are there models to consider that better integrate community-based services beyond the traditional medical system?

We believe that such a model will be important for rural areas. A drawback with the current Advance Payment ACO SSP model is that is does not permit hospital participation with the FQHCs yet in rural areas the community hospital is a significant provider of specialty care and outpatient services. Thus, a model that can allow for multiple community providers to participate is important to develop. We are exploring the development of a Community Care Organization in rural northern NH to achieve this. This model will be a hybrid of the ACO and historic PHO concepts and will include hospitals, FQHCs, Community Behavioral Health providers, and Home Health providers. We are exploring using a rural health consortium organization to help achieve the necessary community integration. An important element of this model will be to create the appropriate environment for commercial payer populations to be included. Having these excluded will make it very difficult to achieve overall success but might require state and federal involvement to achieve.

2. In certain permissible circumstances, organizations are able to pursue multiple service delivery and payment reform initiatives. Should CMS formalize an accountable care model where various service delivery and payment reform initiatives are combined? More specifically, would there be interest in a model that tests comprehensive primary care within an ACO context and/or an ACO that incorporates episode-based payments. If so, what would the most critical features of such a "layered" ACO be and why?

Yes this would be of interest as a model. A key consideration of a model that would include primary care (potentially on a capitated basis) and risk sharing around other costs of care paid on an episodic basis would be the financial integration of bundled payment and distribution within the ACO having primary care responsibility. Permitting direct payments of the ACO to other providers involved in episodic care within the bundle might be important to allow.

Multi-Payer ACOs

1. How can CMS encourage the adoption of ACO contracts among other payers of Medicare ACOs?

Not sure this is important. As ACO Delivery systems are formed, they will push other payers into a similar contract approach because providers do not practice different standards of care by payer, rather they strive to provide the best care to all patients regardless of insurance. The commitment needed to be successful as a Medicare ACO will compel these ACOs to insist on some type of comparable arrangement with commercial payers to help pay for the substantial infrastructure investment that must be made for an ACO and its participants to perform. Another impediment for commercial ACO development in more rural markets could be the inability to meet minimum attribution criteria. This would certainly be true in markets where there is an older population that is predominately covered by Medicare and in which the local providers have limited commercial populations to draw from.

2. How can CMS and other payers focus reporting of quality measures on the most important priorities while minimizing duplication and excess burden? Ensuring at least a "common core" of

measures can be utilized across all payers would be useful. Perhaps there is a way for CMS to use its direct licensure and state relationships with state department of insurance licensure to compel this adoption of common core. Establishing a "common core" of measures across multiple payors that encompass Medicare, Medicaid, and commercial payors will need to include measures for pediatrics and women and maternal health.