



CMS Part D Update Agenda

- **MIPPA Prompt Pay Provisions**
- **MTM**
- **Formulary Topics**
 - CMS-FDA Collaboration
 - Reference-Based Pricing
- **E-Prescribing**
- **Prescriber NPI**



New Part D Prompt Pay Requirements (§423.520)

- **Effective January 1, 2010**
- **Maximum timeframes for payment of “clean” claims submitted by network pharmacies (other than mail order or LTC pharmacies)**
- **Timeframes**
 - 14 days after receipt of “clean” electronic claim
 - 30 days after receipt of an other “clean” claims
- **“Clean”—no defect or impropriety or particular circumstance requiring special treatment**



New Part D Prompt Pay Requirements (§423.520)

- **Date of receipt of claim**
 - Electronic claims—date transferred
 - Other claims—5th day after postmark/time stamp
- **Date of payment of claim**
 - Electronic claims—date transferred
 - Other claims—date submitted to USPS or Common Carrier
- **Electronic Funds Transfer**—must be made available if requested by network pharmacy



Medication Therapy Management

- **2004 Part D Final Rule established requirement to have MTM program.**
- **CMS has been collecting plan-submitted information on program characteristics since 2006**
- **For 2010 CMS has used the plan submitted data to set requirements based on practices common to the majority (>85%) of sponsor programs – eliminating outliers**
- **Forward focus on outcomes measurement**



Medication Therapy Management

- **Opt-Out Enrollment** – mandatory
- **Targeting Frequency** – at least quarterly
- **Targeting Criteria**
 - Multiple Chronic Diseases
 - Multiple Part D Drugs
 - Expected Annual Cost Threshold
- **Services/Interventions**
 - To Beneficiaries and Prescribers
 - Interactive + Comprehensive Medical Review & Monitoring



MTM Outcomes Measurement

- **MTM Monitoring contract awarded through 2010 to assist CMS in monitoring and evaluating Part D sponsors' MTM programs.**
- **Part D MTM Reporting Requirements were expanded beginning 2008;**
 - Part D sponsors are required to submit expanded beneficiary level data;
 - CMS expects to begin more robust analysis of the MTMPs in 2009 including analyzing MTM data with PDE data.
- **Efforts of the Pharmacy Quality Alliance (PQA) and other industry stakeholders may also assist CMS in identifying additional standardized measures that could be measured or reported by all Part D sponsors.**
 - Measures are under development by the PQA including MTM specific measures;
 - Additional measures will be considered for use by CMS for future Part D Plan Ratings.



CMS-FDA Collaboration

- **Since 2006 CMS and FDA staffs have communicated on product regulatory status.**
- **Regulatory status determinations cannot be made through normal processes if NDCs are not listed on FDA NDC Directory as required.**
- **CMS believes it is a best practice for Part D sponsors to consider the proper listing of a drug product with the FDA as a prerequisite for a Part D drug coverage determination.**



CMS-FDA Collaboration

- **CMS and FDA will collaborate on producing a “Non-Matched NDC List”.**
- **CMS expects to post an initial version of the Non-Matched NDC List on the CMS website shortly.**
- **CMS expects to again collaborate with FDA on updated version in the Fall.**
- **Any NDCs on the Fall list would be rejected in PDE processing beginning in 2010.**



CMS-FDA Collaboration

- **The Non-Matched NDC List:**
 - Will not be a CMS coverage determination (i.e., not a determination that the product is not a Part D drug);
 - Will not be a determination that the product is not approved by the FDA;
 - Will not absolve Sponsor from duty to make coverage determinations based on regulatory status at time of dispensing;
 - May not be used per se to justify claim denials.
 - Should be used to set supply chain expectations, terms and conditions.



Reference-Based Pricing

- CMS has incrementally increased visibility of reference-based pricing since 2007.
- Beneficiary advocates report it is not understood by many current beneficiaries.
- Suggests brand is on formulary when it effectively isn't; it is "covered" to a far lesser extent than other brands...
- Except in the case of LIS beneficiaries for whom CMS pays the differential – thus, this tool arguably encourages LIS enrollments while avoiding LIS costs.



Reference-Based Pricing

- **Interferes with cost sharing comparisons**
 - Misleading to consumers who believe brand is covered at its tier brand copay;
 - Cannot be accurately calculated and included in beneficiary cost calculations on Drug Plan Finder, thus creating an unlevel playing field between plans;
 - Complicates CMS formulary coverage and cost sharing analyses; extent of cost shifting cannot be quantified so sponsor can lower premiums at the expense of (hidden) increased cost sharing and, therefore, bias comparisons.



Part D Sponsors must “support” Final e-prescribing standards

- “Foundation” Standards—Part D sponsors must provide eligibility information if requested by prescriber or dispenser
- “Initial” Standards—Part D sponsors must provide formulary and benefit information and medication history if requested by prescriber or dispenser
- Part D sponsors must ensure pharmacy contracts require pharmacy compliance with Part D standards when conducting e-prescribing between-
 - pharmacy and Part D sponsor; and
 - pharmacy and prescriber



Support of E-Prescribing Standards

- **Initial Standards (Effective April 1, 2009)**
 - Formulary and Benefits Information between Prescribers and Part D sponsors
 - Fill Status Notification between Prescribers and Dispensers
 - Medication History among Part D sponsors, Prescribers (and Dispensers)
 - National Prescriber Identifier (NPI) to identify individual health care provider



Pharmacies must comply with Final e-prescribing standards

- E-prescribing is voluntary for pharmacies
- Pharmacies must comply with e-prescribing standards if conducting e-prescribing for Part D covered drugs for Part D eligible individuals
- For Example: NCPDP SCRIPT 8.1 RxFill



Ensuring Adequate Network Pharmacy Participation

- Success requires widespread pharmacy participation in e-prescribing
- Barriers to pharmacy adoption:
 - Low Prescriber Utilization
 - Up-front implementation costs
 - New Transaction fees
- MIPPA Incentive payments aimed at low prescriber utilization



Aligning Incentives between Pharmacies and Part D Sponsors

- **Pharmacy e-prescribing costs for Part D drugs for Part D eligible individuals are legitimate Part D overhead costs therefore pharmacy e-prescribing costs should be factored into dispensing fees**
- **Differential dispensing (or incentive) fees for e-prescriptions could further align incentives**
 - Implement e-prescribing software
 - Acquire prescriber NPI
 - Identify Prescription Origin Code on claims



E-Rx - Looking Ahead

- **Increase visibility of pharmacies and prescribers conducting e-prescribing by indications in Part D & C Provider Directories.**
- **Collect Prescription Origin Code on claims by 2010.**
- **Establish e-prescribing reporting requirements for Part D sponsors.**
- **Continue to work through NCPDP on the development of new and/or revision of existing Part D e-prescribing standards.**



Prescriber NPI on Pharmacy Claims

- Part D sponsors must obtain prescriber IDs on all pharmacy claims
- As of May 23, 2008, the pharmacies must use the individual prescriber NPI when it is available
- CMS currently prohibits Part D sponsors from using POS hard edits on non-NPI prescriber IDs

Questions?