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.
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 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.
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.
- 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?