

**Update on Medicare Part D:
2009 and Beyond**

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Outline of Presentation

- » Introduction/Background on Part D
- » Trends in Part D
- » Where We Are Now - Contracting Challenges for Pharmacies
- » Where We Are Going:
 - Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)
 - Changes for 2010 and Beyond
- » Fraud and Abuse
- » Questions and Answers

Medicare Part D Background

- » Title I of the MMA
 - Added Sections 1860D-1 through 1860D-42 of the Act
- » Two types of Medicare prescription drug plans:
 - Standalone PDPs
 - MA-PDs (e.g., HMOs, PPOs)
- » Enrollment is voluntary for most beneficiaries
- » Dual eligibles no longer have drug coverage through Medicaid. Full benefit dual eligibles can be auto-assigned to a PDP.

Trends in Part D

» 2006 – 2008

- Government focus on implementing Part D and working out the “kinks” (e.g., initial enrollment fiasco)

» 2009

- Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)
 - Big changes for Medicare Advantage (Part C)
 - Some changes to Part D

Trends in Part D (cont'd)

» 2010:

- New and expanded obligations for Plan Sponsors
 - Quality Assurance and Medication Management Programs
 - Reporting
 - Audits
- More accountability for Plan Sponsors
 - Demand for more accuracy and completeness in filings

Trends in Part D (cont'd)

» 2010 (cont'd)

- Greater transparency for beneficiaries
- Mixed bag for network pharmacies
 - MIPPA changes effective 1/1/2009 and 1/1/2010 will be helpful, but
 - “Trickle down” effect of increased obligations on Plan Sponsors for network pharmacies and other Part D players

Where We Are Now: Contracting Challenges for Retail Pharmacies

- » Access to Retail Pharmacies: Plan Sponsors must secure the participation in their pharmacy networks of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure enrollees' convenient access to covered Part D drugs.
- » Inclusion of mail-order pharmacies in Part D network is optional.
 - Part D requirements seek to “level the playing field” between mail-order and retail pharmacies:
 - Reasonable access to extended supplies at network retail pharmacies
 - Gap coverage must be available to enrollees at all network pharmacies

Limited Access and “Specialty” Drugs

- » Limited access to a Part D drug may not be based solely on the placement of a Part D drug in a specialty or high-cost tier because this tier placement alone is not indicative of any special requirements associated with such drug.
- » Plan Sponsors may only restrict access to Part D drugs to a subset of their network pharmacies for the following reasons:
 - The FDA has restricted distribution of the drug to certain facilities or physicians; or
 - Appropriate dispensing of the Part D drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy.

Limited Access and “Specialty” Drugs (cont.)

- » Plan Sponsors may not require network pharmacies to qualify as a “specialty” pharmacy in order to dispense any drug that requires special attention if the network pharmacy is capable of appropriately dispensing the particular Part D drug.
 - “Specialty” pharmacies can be used to supplement network pharmacy access when necessary and not otherwise restrict the network.

Any Willing Pharmacy Requirement

- » Plan Sponsor must permit the participation of any pharmacy that is willing to accept the sponsor's standard terms and conditions.
 - Standard terms and conditions must be “reasonable and relevant.”
 - Whether Plan Sponsor has permitted a pharmacy an opportunity to participate in its network, or whether a pharmacy can meet or has met contract terms are fact-specific questions “that are generally best left between the parties.”

Standard Terms and Conditions

- » Standard terms and conditions, particularly for reimbursement terms, may vary to accommodate geographic areas or types of pharmacies, provided that all similarly situated pharmacies are offered the same standard terms and conditions.
 - Standard terms and conditions are the “floor” of minimum requirements that all similarly situated pharmacies must abide by.
 - Plan Sponsors may modify some of their standard terms and conditions to encourage participation by particular pharmacies.

Preferred vs. Non-Preferred Pharmacies

- » Plan Sponsors may establish distinctions between “preferred” and “non-preferred” pharmacies within their pharmacy networks.
- » Pharmacy can only be designated as preferred if it offers enrollees a lower level of cost-sharing than a non-preferred pharmacy.
- » Cost differential cannot deter beneficiaries in certain areas from enrolling.

CMS Required Clauses for Network Pharmacies

- » Abide by all applicable Federal laws and regulations and CMS instructions
- » Abide by State and Federal privacy and security requirements
- » Give HHS, the Comptroller General, or their designees the right to audit, evaluate and inspect any books, contracts, records, including medical records and documentation involving transactions related to CMS' contract with the Part D sponsor and agree that these rights continue for a period of 10 years from the final date of the contract period or the date of audit completion, whichever is later.
- » Hold enrollee harmless for amounts due by Plan Sponsor
- » Agree that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to either the Plan Sponsor to provide to CMS or its designees or will be provided directly to CMS or its designees.
- » Inform Part D enrollee at the point of sale (or at the point of delivery for mail order drugs) of the lowest-priced, generically equivalent drug, if one exists for the beneficiary's prescription, as well as any associated differential in price.
- » Provide Part D enrollees access to negotiated prices
- » Charge/apply the correct cost-sharing amount.

Where We Are Going: Medicare Improvements for Patients & Providers Act of 2008 (MIPPA)

» Part D Pricing Updates – effective 1/1/2009

- Mandates updates of prescription drug pricing standard (e.g., AWP) used for network pharmacy reimbursement at least every seven days beginning with initial update on 1/1 of each year
- Pricing standard update must be in the network pharmacy contract as well as the source used by Plan Sponsor for making price updates

MIPPA (cont'd)

» Prompt Payment of Pharmacies

- Imposes prompt payment requirement for clean claims under Part D (including MA-PD) – effective 1/1/10
 - For retail pharmacies, payment must be issued, mailed or otherwise transmitted for all clean claims submitted by or on behalf of pharmacies within 14 days for electronic claims and within 30 days for claims submitted otherwise
 - Interest due on late paid claims
 - Claim is “deemed clean” if notice of deficiency not provided within 10 days for electronic claims and 14 days for other claims
 - Electronic payment required if requested by pharmacy

2010 and Beyond

» Increased Transparency

- Elimination of “lock-in” pricing as basis for determining beneficiary cost-sharing and reporting drug costs to CMS
 - Actual amount paid to the pharmacy by PBM must be used in determining beneficiary cost-sharing and reporting drug costs to CMS (i.e., the pass-through price)
- Website postings: Plan Sponsors must post prior authorization (PA) requirements on websites in 2010 as well as post quantity limit restrictions and step therapy requirements. All utilization management requirements applied to formulary drugs, including quantity limit amount, quantity limit days supply, PA criteria and step therapy criteria, must be available on Plan Sponsors’ formulary websites for display by November 15, 2009.

2010 and Beyond (cont'd)

» Utilization Management Criteria

- For contract year 2010, drugs with prior authorization or step therapy requirements must have corresponding utilization management criteria filed with and approved by CMS.
 - P&T Committee Review
 - Lack of access to FDA labeled indications
 - Use of “off-label” indications

» Elimination of Reference-Based Pricing

- Programs that require enrollees to pay defined cost-sharing amounts plus supplemental cost-sharing based on cost differential between dispensed drug and lower-cost preferred alternative (e.g., generic) will be eliminated

New Requirements for Medication Therapy Management (MTM) Programs

- » Beginning in 2010, Part D sponsors will be required to implement MTM programs that:
 - Enroll targeted beneficiaries using an opt-out method of enrollment only
 - Target beneficiaries for enrollment at least quarterly during each year

New MTM Program Requirements

- Target beneficiaries who:
 - Have multiple chronic diseases, but Plan Sponsors can't require more than three chronic diseases as minimum and must target at least four of seven core chronic conditions;
 - Are taking multiple Part D drugs, but Plan Sponsors can't require more than eight Part D drugs; and
 - Are likely to incur annual costs for covered Part D drugs that exceed \$3,000

MTM Program Requirements (cont'd)

- Offer interventions to beneficiaries and prescribers.
 - Offer comprehensive medical review (CMR) by a pharmacist or other qualified provider at least annually to all targeted beneficiaries enrolled in the MTM program including:
 - Review of medications to assess medication use and identify medication-related problems;
 - Offer to provide an interactive, person-to-person consultation performed by a qualified provider; and
 - Implement systematic process to summarize the interactive consultation and provide an individualized written “take-away” to the beneficiary.

MTM Program Requirements (cont'd)

- For ongoing monitoring, perform targeted medication reviews no less often than quarterly, to assess medication use since the CMR, monitor whether any unresolved issues need attention, new drug therapy problems have arisen, or if the beneficiary has experienced a transition in care.
- Offer interventions targeted to prescribers to resolve medication-related problems or other opportunities to optimize the targeted beneficiary's medication use.

MTM Program Requirements (cont'd)

- Measure and report details at the beneficiary level on the number of comprehensive medication reviews, number of targeted medication reviews, number of prescriber interventions, and the change(s) in therapy directly resulting from MTM interventions.
- » Will these changes make MTM Programs more effective?
 - March 2009 Medpac report
 - More community pharmacy involvement

But Wait – There’s More Coming

» Quality Assurance Requirements

- Plan Sponsors are required to establish quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use. CMS is adding new “expectations” and details on:
 - Concurrent drug utilization review
 - Retrospective drug utilization review
 - Medication error identification and reduction

But Wait – There's More Coming

» New Medicare Secondary Payer Edits

- Plan Sponsors must make conditional payments for workers' comp, black lung, and no-fault/liability insurance, and then recover mistaken payments.

» Claims for Drugs Prescribed by Excluded Providers

- Won't result in reversal of claim, but subsequent claims will be denied

Medicare Fraud And Abuse

Government Enforcement

- **Dramatic Growth Of Enforcement Actions Continues**
- **In First Half Of 2009, OIG Alone Accomplished:**
 - \$2.4 Billion in fraud & abuse recoveries
 - Excluded 1,415 people and companies
 - Started 293 criminal actions, 243 civil actions
 - Well ahead of 2008
- **HHS, CMS, OIG & DOJ Recently Formed “HEAT”**
 - Healthcare Enforcement Action Team focused on Medicare
 - Expands “Medicare Fraud Strike Forces”
 - Increases site visits during DME provider enrollment process
 - More funding for MEDICS

Expansion Of False Claims Act

- **2008: Supreme Court Decision**
 - FCA applies only if ask government to pay false claim
 - Pharmacies ask Part D plans to pay, not government
- **2009: Fraud Enforcement And Recovery Act**
 - FCA applies if government pays indirectly (e.g., Part D)
 - Keeping overpayment can be “reverse false claim”
 - Important due to burdens of private “qui tam” lawsuits

Training Requirement

- **Rule Requires Annual Fraud & Abuse Training**
 - Must complete initial training by end of this year
- **“Specialized” Training For Pharmacists**
 - Train employees involved in Medicare services & billing
 - Train everyone else too??
- **Confusion Regarding Who Provides Training**
 - For years CMS said pharmacies can provide training
 - Oct. 2008: CMS said plans provide & CMS would endorse
 - Feb. 2009: CMS said it won't endorse & will clarify “soon”
 - Most pharmacies use own training or NACDS Foundation