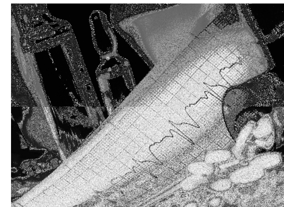
HCCA Medicare Part D Conference
Part D Price Transparency
December 8, 2008
2:15-3:15 p.m.



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Agenda

- Overview and Introduction
- Update on Part D Price Transparency Issues
  - How is Price Transparency defined/DIR Changes
  - Part D Plan Pricing disclosure requirements
- Part D Macro/Micro Processes and Pricing Risk Areas
- Part D Competitive Cornerstone
- Call to Action for CMS and Other Part D Audits from GAO and OIG
- What Plan Sponsors Can Do to Prepare Now
- MIPAA and New Administrative Part D Changes
- Summary and Questions/Answers

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Overview and Introduction

- After almost 3 years of the Part D Program, initial implementation challenges have given way to waves of change associated with the Medicare Improvements for Patients and Providers (MIPAA) Act of 2008.
- Past criticism of the Part D Program's cost savings and enforcement of transparency as proof of those savings has sharpened.
- A new political climate seems poised to take that criticism and fold into potentially significant Part D Program changes.
- As past pricing requirements remain in tact, CMS has re-affirmed its expectation that health plans to audit and monitor their Part D programs (including the activities of first tier and downstream entities such as PBM's, manufacturers and pharmacies) to the standards set forth in revised regulations and compliance guidance.
- Failure to monitor compliance risks will subject Part D participants (including contractors and other downstream entities) to heightened scrutiny under federal and state law, including potential whistleblower claims, criminal and civil penalties and corporate integrity agreements.

Price Transparency Issues

Part D Drug Costs

- One of the main differences between the Part D program and commercial programs' drug coverage is the level of transparency that is required by CMS. This transparency is especially different for the pharmaceutical manufacturer rebates and pricing decisions made by PBMs.
- CMS reimburses plan sponsors for Part D drug costs that are "actually paid" or net of any indirect or direct remuneration ("DIR") through allowable reinsurance and risk corridor costs.

What is Price Transparency?

Part D Drug Costs

- Per 42 C.F.R. Section 423.308, **DIR** is any and all rebates, subsidies, or other price concessions from any source (including manufacturers, pharmacies, enrollees, or any other person) that serve to decrease the costs incurred by the Part D sponsor (whether directly or indirectly) for the Part D drug. Thus, DIR includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, and coupons. DIR also includes goods in kind, free or reduced-price services, grants, **legal judgment amounts**, **settlements amounts from lawsuits or other legal action**, and other price concessions or similar benefits. **However, rebates and other price concessions which are not considered to directly or indirectly impact the drug costs incurred by the Part D sponsor are not included in DIR.**
- CMS issued revised DIR reporting guidance on 6/13/08 to state that “bona fide” service fees that Part D sponsors or their subcontractors (e.g. PBMs) receive from manufacturers are not price concessions and hence not DIR.

What is Price Transparency? (Cont’d)

Part D Drug Costs

- CMS defined bona fide services fees consistent with the July 2007 Final Rule on Medicaid Drug Pricing as:
  - Those paid by a manufacturer to an entity that represent fair market value for an itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.
- If a rebate administration fee meets this definition it is not DIR and is excluded from the DIR report made to CMS by plan sponsor.
- Also, if an administrative fee exceeds FMV, that differential between the overage and FMV must be reported as DIR.

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What is Price Transparency? (Cont'd)

Manufacturer Rebates, Pricing Decisions, and Transparency

- The CMS 2007 Call Letter still applies which stated that a plan must report 100% of the remuneration it receives including any PBM price concessions. Further, this included reporting 100% of the manufacturer rebates paid for Part D drugs including the portion of such rebates retained by the PBM as part of the price concession for the PBM's services (except for bona fide service fees).
- Another revision in the 6/13/08 CMS DIR guidance is that Part D sponsors must report Legal judgments and settlement amounts (including those from manufacturers) which directly or indirectly impact Part D drug costs a DIR. They can exclude certain legal fees associated with these judgments/settlements.
- All of these changes mean that Health plans must insist that their PBM and/or manufacturer provide the level of data necessary to support an audit of rebate and discount transactions and drug pricing decisions.

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Part D: Pricing Disclosure Requirements

- Part D requires disclosure of pricing information to CMS and plan beneficiaries.
- Sponsors must provide beneficiaries with access to negotiated prices that are free of all price concessions (i.e., direct and indirect subsidies, rebates, remunerations and any other price concessions plans obtained from pharmacies and manufacturers).
- Sponsors must ensure that contracting pharmacies inform enrollees of the differential between the price of the dispensed drug and the lowest priced generic drug at the point of sale (or at time of delivery for mail order).
- Sponsors also must provide ongoing reports of all rebates and administrative fees (except for bona fide admin. svc. fees and certain legal fees) to CMS. Congress has reviewed this data for the first years of operation under Part D.

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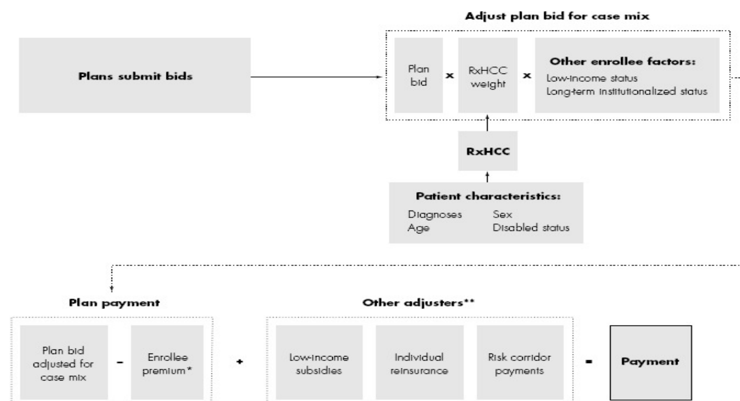
Part D Price Transparency Macro and Micro Processes and Risk Areas

Overview of the Plan Bid Process

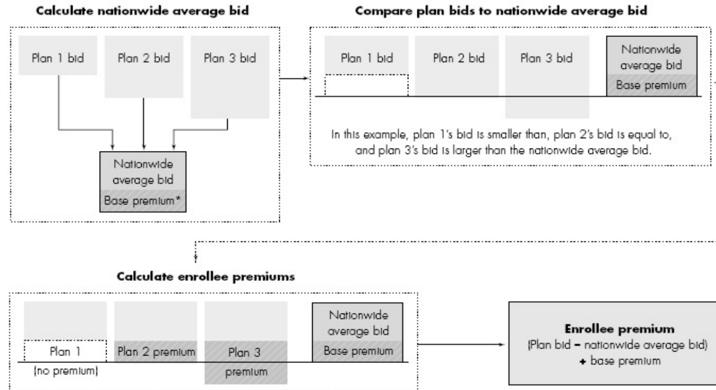
Part D Bid and Payment System[2]



(2) MEDPAC paymentBasics. Part D Payment System. Oct 2007. pg 3

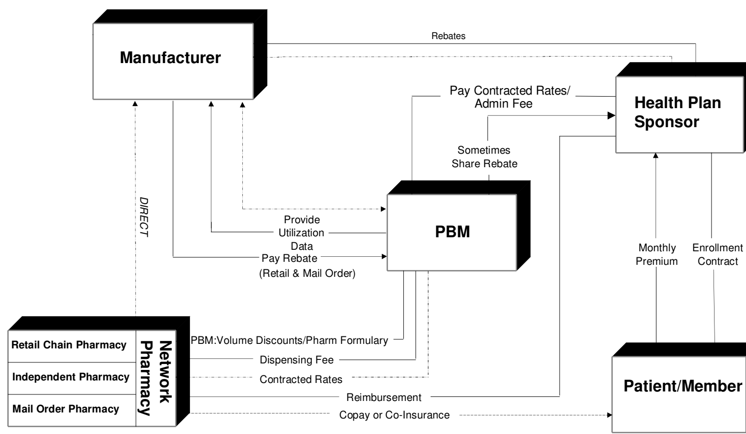
Overview of the Plan Bid Process (Cont'd)

Enrollee Premiums[3]



(3) MEDPACpaymentBasics. Part D Payment System. Oct 2007. pg 4

PBM Formulary Rebate Process



Year-End Payment Settlement Process

- CMS reconciles actual levels of enrollment, risk factors, levels of incurred allowable drug costs (after rebates and other discounts), reinsurance amounts, and low-income subsidies at year end.
- CMS risk adjusts actual member plan premiums based on plans submitting PDE data throughout the year. At year end, CMS reconciles the PDEs and determines reinsurance amounts and risk corridor applications.
- Accurate and complete PDE submissions are critical, as this data is required to track true drug costs and an accurate Bid for the upcoming year. PDE rejects must all be worked and reconciled internally and with CMS so that bids are not underpriced.
- CMS reconciles direct and indirect remuneration at year end. CMS expects for plans to understand and report correct drug costs while excluding appropriate service fees and non-drug related fees.
- On-going membership reconciliation will allow for appropriate reporting, reduced PDE rejects and accurate TrOOP reporting for members.

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Competitive Cornerstone of Part D

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Competitive Cornerstone of the Part D Regulations

- Competition among plan sponsors via "bidding" to CMS for reimbursement as well as competitive negotiations for prescription drug prices are cornerstones of the current Part D Program.
- CMS is currently expressly prohibited from interfering with these competitive negotiations among private entities (this is source of debate in terms of Obama plans).
- Part D provides that these negotiated prices with manufacturers will be excluded from Medicaid "best price" calculations.

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Competitive Cornerstone of the Part D Regulations Open for Debate

- A GAO report released on 2/9/07 compared the drug prices obtained under Part D by private health plans to those achieved under Medicaid and other government programs.
- Committee Chair Henry Waxman (D-CA) sent letters to the top 12 PDP plans asking for detailed information about prices paid for prescription drugs, including administrative costs, profit and all discounts or price concessions, to determine how these discounts and price concessions were passed on to beneficiaries.
- The primary issue was to determine whether CMS should directly negotiate drug prices under Medicare Part D rather than the plans.
- Economic testimony suggested that this direct government intervention should occur only if the market fails.

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Competitive Cornerstone of the Part D Regulations Open for Debate (Cont'd)

- The main finding from the Committee on Oversight and Government Reform report (October 2007) was that Part D plans had higher than average administrative costs and low rebates.
- The report stated that rebates only reduced drug spend by 8.1% in 2007 which was much less than the 26% earned by Medicaid or the VA's 50%.
- The report also stated that Part D was a "significant windfall for pharmaceutical manufacturers." They noted this windfall was most significant for dual eligibles (Medicare/Medicaid members).

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CMS Call to Action from Other Agencies

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CMS Call To Action from Other Agencies is Clear

- Since October 2007 GAO reports on bid/payment audits stated they had limited utility in recovery efforts.
- October 2007 House Oversight/Reform Committee reported on Medicare Drug Plans' high expenses and low rebates.
- This work continued by GAO who reported in September 2008 on CMS oversight of plan reported price concession data.
- OIG reported in November of 2008 that bid and financial audits had still not fully commenced and lacked regulatory teeth to impact changes and bring savings in cost.

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GAO Report on Price Concessions and Financial Audit

- The 9/08 GAO report on Federal Oversight of Price Concessions stated:
  - Since DIR Reports are used to calculated payment, they are subject to the CMS 1/3 payment audit program.
  - Plans also provide quarterly rebate reports but they only contain data from manufacturers while the annual DIR report has data from other entities such as pharmacies.
  - Per the report, CMS had to complete 169 payment audits by October 2008.
  - The goal of the CMS financial audits was to conduct the following data checks:
    - Comparison of 2006 DIR data with that reported in 2008 bid
    - Comparison of 2006 DIR data with quarterly rebate reports
    - Checks for outliers.
- CMS acknowledged that Fair Market Value for administrative fees and other concepts of DIR were difficult to audit due to the vast array of Plan to PBM contract terms and service definitions.

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OIG Report on Part D Bid Audits

- There are two types of Bid audit findings:
  1) Material – significant issues that if corrected would affect payments or beneficiary benefits.
  2) Observations – other non-material findings used to help refine the bid process for the future years.

  Findings and Recommendations:
- OIG found that 25% of 104 bid audits performed for plan years 06 and 07 identified at least one material finding.
- The largest number of findings involved non-pharmacy costs and methodology errors.
- Bid audits are not designed (due to timing issues) to adjust bid amounts or lead to sanctions.
- OIG has recommended that CMS 1) modify the way it responds to bid audits and/or 2) revise the bid process.

2009 OIG Work Plan – Pricing Focus

In tightening fiscal and new political times, the trend toward increased MA and Part D audit scrutiny continues.

Part D Reconciliation Calculations	OIG will review CMS' reconciliation calculations for Part D sponsors were performed in accordance with regulations.
Part D Data Submitted by Sponsors for Reconciliations	OIG will review the accuracy of plan submitted data submissions for reconciliation purposes. This will include accuracy of PDE and Direct and Indirect Remunerations data.
Oversight of PBMS	The review will determine whether CMS and Plans conducted proper oversight of PBMs for Part D functions. This will include review of PBM to plan contracts, and a determination of whether they contained required provisions to comply with Federal regulations.

2009 OIG Work Plan – Pricing Focus (Cont'd)

Bid Submission by Part D Sponsors	OIG will take a different focus on bids in 09 performing a review of how well plans followed CMS Bid Instructions including reporting of all price concession estimates. OIG will also look to make sure that negotiated prices were properly supported.
Part D Negotiated Prices and Price Concessions	OIG will review whether plans passed on all price concessions (including those discounts at the pharmacy point of sale, direct or indirect subsidies, rebates and other price concessions and direct and indirect remuneration). This review will also examine CMS' oversight of plans disclosure and pass-through of these price concessions.
Part D Sponsors Audits of Pharmacies	In an important downstream oversight turn, OIG will review Plans and their PBMs pharmacy audit activities. They will also review any amounts recouped from the pharmacies and determine whether they were reported as overpayments to CMS.

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What Plan Sponsors Can do Now to Prepare

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Step 1: Assess Relationships with Contractors and Sub-Contractors

- Based on the typical level of delegation of Medicare Part D responsibilities, sponsors must oversee third parties to which responsibilities are delegated, as the plan is ultimately responsible to CMS for the performance of the delegate.
- Plans may require in their contracts with delegates (including PBMs and manufacturers) more specific oversight language such as:
  - Specification of delegated responsibilities and reporting responsibilities
  - Provisions for revocation or other remedies if the delegate is not meeting contractual obligations
  - Provisions for Part D Sponsor ongoing monitoring and auditing
  - Statements that the Contractor or Subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions
- Plans attest to CMS a level of transparency that must be tested at the first tier delegate and sub-contractor levels.

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Step 2: Understand What May Be New Risk Areas

- **Bid Risk**
  - Heavy use of delegation and lack of Internal Audit/Compliance focus.
  - Plans should have an internal actuarial department that can work to vet and verify the accuracy of data/information given to outside actuaries.
  - Plans need a sign off protocol on the bid and underlying data prior to outside actuarial certification.
- **Data Integrity**

  Data that underpin bid and payment reconciliation should be key on any Part D audit and compliance plan
    - PDE, ongoing Part D pharmacy claims data, rebate and price concession data,
    - COB and TrOOP
  - These data should be analyzed to Analyze claims data to identify potential errors, inaccurate TrOOP accounting and provider billing practices;
  - Identify over-utilization; and
  - Identify problem areas at the subcontractor level (e.g. PBM, pharmacy and pharmacists).
- The plan's focus should be to audit the entire contractual and financial drug supply chain.

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Step 3: Incorporate Different Types of PBM Audits

Claims Processing and PDE Reconciliation

- Electronic reviews are performed to "re-price" the Plan Sponsor's claims history and ensure that the PBM is applying the correct drug unit pricing and other formulas per the PBM contract and Part D requirements; and,
- Detailed testing audits of a random sample of claims are performed to ensure proper handling of mail versus retail claims, eligibility, COB, duplicate flagging, dispensing fees, formulary compliance, fraudulent claims, etc.
- Ongoing PDE Reconciliation should be performed in aggregate and on a sample basis to test detail behind calculations and system programming.

Formulary Rebates

- Measure the ability of a PBM to obtain and recover rebate amounts from manufacturers and pass the appropriate portion back to the Plan Sponsor in accordance with terms reported to CMS.

Other - Administrative or Clinical

- Measure the extent to which the PBM has complied with any performance guarantees included as part of the contract, such as ID card and mail service production turnaround time, dispensing accuracy, customer service response time, etc.

Part D MIPAA and Obama Plan Changes

Obama Reform Impact on Specific Federal Programs

Program	Immediate Impact of New Administration
Medicare Advantage and Part D	• Reduced margins as subsidies reduced or eliminated • Disclosure of administrative costs •Limits on price increases • Increased requirements for generic prescriptions • Direct contracting with drug companies •Risk pool issues associated with pre-conditions • Additional requirements of disease management and other programs

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MIPAA Part D Reform: Drug Pricing Standards

- Effective 1/1/09, Part D sponsors must update the drug pricing standards used for pharmacy reimbursement on at least a weekly basis, with an initial update on January 1st of each subsequent year.
- Sponsors must ensure that any contracts or written agreements with pharmacies or other providers (including first tier, downstream and related entities) include provisions for regularly updating these standards
- Sponsors must amend their current PBM and pharmacy contracts consistent with this new requirement to the extent these contracts address regular pricing standards
- Sponsors must ensure that they design internal processes so that fee schedules tied to any drug pricing standards are updated within these timeframes and adjudicated with proper fee schedule

Plan Implications and Next Steps:
•PBM and downstream entity contracts must be reviewed and amended to include required provisions
•Internal processes must include quality checks to ensure that appropriate fee schedules are used when claims are adjudicated

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MIPAA Part D Reform: Claims Timeliness, Clean Claims & Receipt Dates

- Starting in 2010, all Part D plans must adjudicate "clean claims" from retail pharmacies (excludes mail order and LTC) within the following time frames:
  - Within 14 days of receipt for claims submitted electronically.
  - Within 30 days if non-electronic/paper.
- Date of receipt for electronic claims is the date the claim is transferred to the plan via EDI.
- Date of receipt for non-electronic is the 5th day after the postmark on the claim, or the actual date stamp of the transmission for any claim, whichever is sooner.

MIPAA Part D Reform: Claims Timeliness, Clean Claims & Receipt Dates (Cont'd)

- Clean claims are defined as a claim that has no impropriety or defect or particular circumstance requiring special treatment that prevents payment from being made timely
  - Claims are deemed to be clean if Part D sponsor does not notify the claimant of any defect or impropriety within 10 days of receipt
- Also, in Plan Year 2010, Long Term Care Pharmacies have no less than 30 days and no more than 90 days to submit claims to a Part D sponsor
  - Timeframes for claims submissions must be included in the Part D sponsor contracts with the long-terms care pharmacies

MIPAA Part D Reform: Interest Payments & Dates of Payment

- Request interest payments at a specified rate if claim is not paid timely
- Interest is calculated at a rate equal to the weighted average of interest on a 3-month marketable Treasury securities determined for such period and increased by 0.1 % for the period beginning on the day after the required payment date
- Interest payments will not be counted as Part D sponsor administrative costs or allowable risk corridor costs and, therefore, must not be included in DIR calculations
- Date of Payment is:
  - Date payment is transferred for electronic claims
  - Date payment is mailed for all other claims

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MIPAA Part D Reform: Interest Payments & Dates of Payment (Cont'd)

- MIPPA prohibits Part D sponsors from retaliating against an individual or provider who exercises these payment rights.
- MIPPA requires that Part D plan sponsors pay all clean claims submitted electronically by electronic transfer of funds if the pharmacy requests or has made a previous request. If payment is made electronically, remittance by the Part D plan sponsor may also be made electronically.

Plan Implications and Next Steps:

•Plans will need to begin re-working contracts with PBMs and pharmacies to reflect these claim turnaround times.

•Plans must improve the ability to segregate electronic and paper claims and be able to report timeliness measurements for both.

•Plans will also have to develop performance metrics to ensure that the activities of claims delegates do not weigh down plan compliance of the new timeframes.

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Wrap-Up and Q&A

- Entities that are in some way contracted or providing Part D benefits and services will have to remain flexible in light of the state of flux of the Part D drug pricing provisions.
- Early 2009 will be a time of intense scrutiny, a changed regulatory and political landscape and perhaps enforcement actions.
- Plans, PBMs, manufacturers, and other entities should be prepared for increased CMS, GAO, OIG, and other pricing information requests and audits.
- These entities should make sure they have:
  - Conducted a baseline risk assessment/gap analysis against compliance and pricing disclosure requirements.
  - Conducted a similar review of the applicable contracted PBM's compliance and pricing risk areas.
- Plans should expect regulatory and enforcement scrutiny of their Part D activities analogous to similar activity under existing government programs such as Medicare Part B and the Medicaid drug rebate program.

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Questions

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