Hot Topics in Health Policy: Focus on Medicare Part D Redesign and PBM Reform

Adam Finkelstein, JD, MPH
Counsel
Manatt, Phelps & Phillips LLP

Ross Margulies, JD, MPH
Partner
Manatt, Phelps & Phillips LLP

AMCP

Learning Objectives

1. Explain the latest updates to the Inflation Reduction Act (IRA) and the possible impact on managed care pharmacy practice.
2. Apply the tips provided to ensure your Medication Prescription Payment Plan complies with the Centers for Medicare and Medicaid Services (CMS) regulations and understand how the MPPP program impacts different beneficiary profiles.
3. Define the various perspectives around pharmacy benefit manager reform and the rationale for legislative action.
4. Explain the most likely legislative activities related to PBM reform to be approved and the impact on PBMs.
5. Using case studies, describe the impact of PBM legislation on various supply chain stakeholders.

Continuing Pharmacy Education Credit

The Academy of Managed Care Pharmacy (AMCP) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity is accredited to provide 1.25 contact hours of continuing pharmacy education (CPE) credit.

- ✓ **Instructions to claim credit can be found in the app**
- ✓ **Obtain the session access code**
- ✓ **Login to amcplearn.org**
- ✓ **Submit by Monday, November 11, 2024**

Financial Relationship Disclosures

Faculty/Reviewer/Planner	Reported Relevant Financial Relationships
Adam Finkelstein, JD, MPH *Faculty*	Disclosed no relevant financial relationships.
Ross D. Margulies, JD, MPH *Faculty*	Disclosed no relevant financial relationships.
Alyza King, PharmD *Reviewer*	*Employee:* CVS Health (Caremark)
Brittany V. Henry, PharmD, MBA *Planner*	Disclosed no relevant financial relationships.

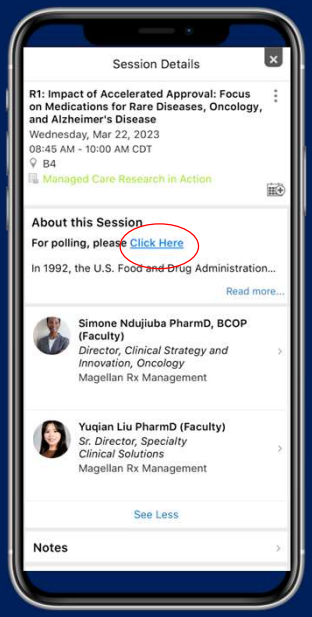
- If applicable, relevant financial relationships have been mitigated and documented.
- Content has undergone a peer review to ensure content validity.

AMCP Antitrust Guidelines

- AMCP's policy is to comply fully and strictly with all federal and state antitrust laws
- Nothing in this presentation should be interpreted as encouraging or suggesting collective action
- This session will be monitored for any antitrust violations and will be stopped by the session monitor if any such violation occurs
- Please refer to the final program or **www.amcp.org/antitrust** for more information

Participate in Polls and Ask Questions

https://nexus24.cnf.io/sessions/wbe3



Housekeeping Information

- Use the QR code to access the handout
- After attending all of today's program, participants are eligible to earn 3 hours of CPE
- Please be sure to silence your phones and any other electronic devices, but don't forget to post to social! **#AMCPNexus**
- Participate!

Faculty

Adam Finkelstein, JD, MPH

Counsel,
Manatt, Phelps & Phillips LLP

Ross Margulies, JD/MPH

Partner,
Manatt, Phelps & Phillips LLP

Inflation Reduction Act (IRA) Update

IRA's First Negotiated Prices Announced

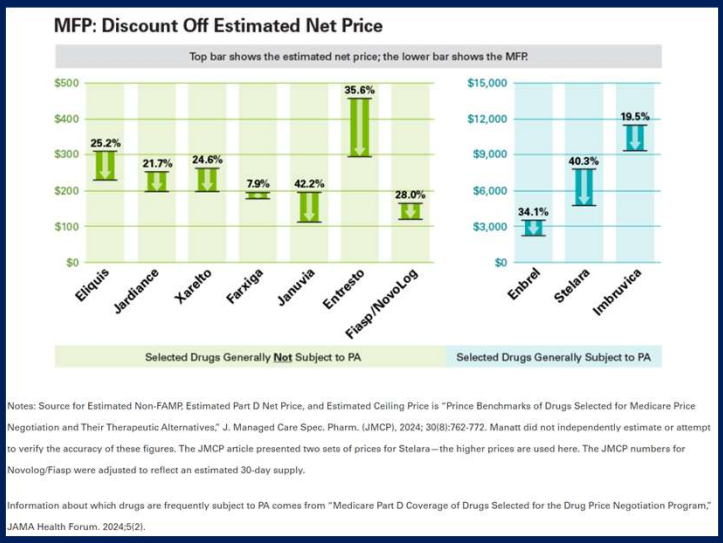
CMS announced prices for first 10 negotiated drugs, touting savings; however, data suggests discounts are modest.

Drug	Manufacturer	Estimated Ceiling Price*	MFP	MFP: Discount Off Estimated Ceiling Price
Eliquis	Bristol Myers Squibb	$309.00	$231.00	25.2%
Jardiance	Boehringer Ingelheim and Eli Lilly	$251.70	$197.00	21.7%
Xarelto	Janssen	$261.30	$197.00	24.6%
Farxiga	AstraZeneca	$193.80	$178.50	7.9%
Januvia	Merck	$188.52	$113.00	40.1%
Entresto	Novartis	$442.80	$295.00	33.4%
Stelara	Janssen	$4,605.00	$4,695.00	-1.9%
Enbrel	Amgen	$2,352.00	$2,355.00	-0.1%
Fiasp/NovoLog	Novo Nordisk	$165.28	$119.00	28.0%
Imbruvica	Pharmacyclics (AbbVie) and Janssen	$7,677.00	$9,319.00	-21.4%

*Due to these amounts being confidential, there is no way to capture the difference between the ceiling price and the MFP with absolute accuracy.

MFP = maximum fair price; Sources: "Price benchmarks of drugs selected for Medicare price negotiation and their therapeutic alternatives" Manag Care Spec Pharm. 2024;30(8):762-72, https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation

MFP: Discounted Off Estimated Net Price



Notes: Source for Estimated Non-FAMP, Estimated Part D Net Price, and Estimated Ceiling Price is "Prince Benchmarks of Drugs Selected for Medicare Price Negotiation and Their Therapeutic Alternatives," J. Managed Care Spec. Pharm. (JMCP), 2024; 30(8):762-772. Manatt did not independently estimate or attempt to verify the accuracy of these figures. The JMCP article presented two sets of prices for Stelara—the higher prices are used here. The JMCP numbers for Novolog/Fiasp were adjusted to reflect an estimated 30-day supply.

Information about which drugs are frequently subject to PA comes from "Medicare Part D Coverage of Drugs Selected for the Drug Price Negotiation Program," JAMA Health Forum. 2024;5(2).

Timeline for the "Negotiation Process" for IPAY 2026

2023				2024				2025	2026
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q1
Spring 2023: CMS publishes Drug Price Negotiation Process ICR	**June 2023:** CMS publishes Revised Negotiation Guidance for IPAY 2026	**Sept. 1, 2023:** HHS publishes selected drug list **Oct. 1, 2023:** Negotiation period begins by this date. **Oct 1, 2023:** Manufacturer deadline for entering into an agreement **October 2, 2023** Manufacturer deadline for submission of initial data.		**Feb. 1, 2024:** CMS sends written initial offer to Primary Manufacturer by this date **30 days after receipt of initial offer:** Primary Manufacturer accepts offer or proposes optional written counteroffer	**30 days after CMS receipt of counteroffer:** CMS accepts counteroffer or holds negotiation meeting with Primary Manufacturer (if CMS rejects the counteroffer) **June 30, 2024:** All negotiation meetings end by this date (maximum of 3 meetings allowed)	**July 15, 2024:** CMS sends final offer to Primary Manufacturer no later than this date **July 31, 2024:** Primary Manufacturer accepts or rejects final offer **Aug. 1, 2024:** Negotiation period ends **Sept. 1, 2024:** CMS publishes MFP for selected drugs no later than this date		**March 1, 2025:** CMS publishes public explanation for MFPs no later than this date	**Jan. 1, 2026:** MFP effective for selected drugs

Alternatively, the Manufacturer of a selected drug has the option to:
(1) Opt out and pay an excise tax on sales of the selected drug to Medicare; or
(2) Opt out and avoid the excise tax on sales of the selected drug by withdrawing from the Medicare and Medicaid programs.

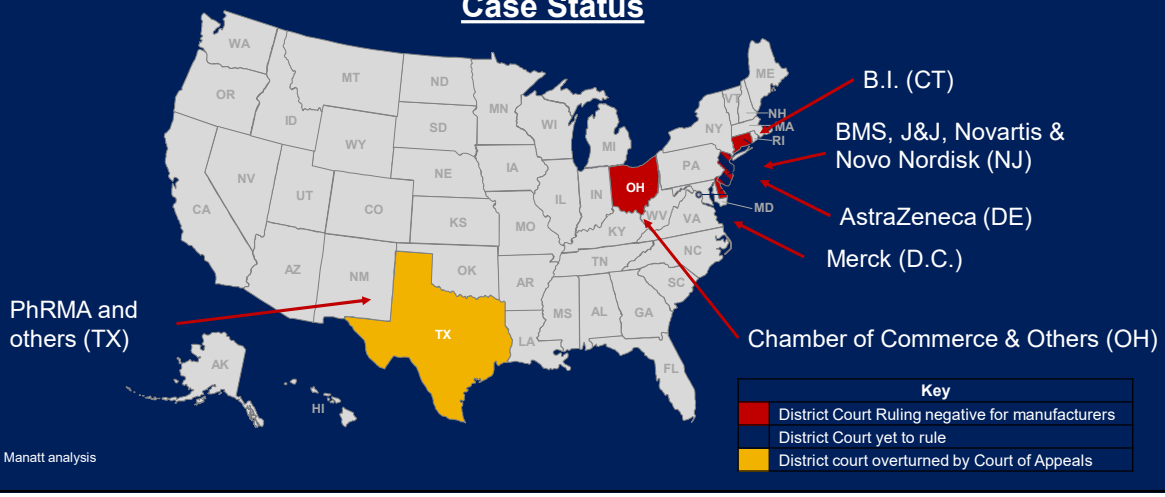
Primary "negotiation period"
Counteroffer process
Process after agreed upon MFP

ICR = information collection request; IPAY = initial price applicability; MFP = maximum fair price;
Source: https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf

Lawsuits Against Negotiation Continue

No court has ruled in favor of challengers on the merits

Case Status



Source: Manatt analysis

Overview of Part D Program Changes (2024, 2025+)

2024

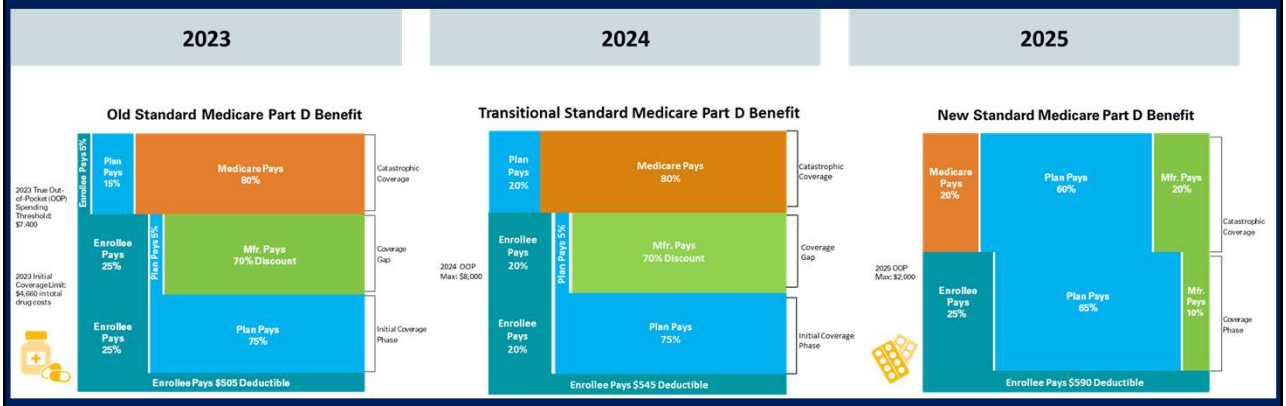
- **No Catastrophic Phase Cost Sharing.** Enrollee cost sharing in the catastrophic phase (after $8,000 in OOP spending) is reduced to zero. Actual brand-drug spending could be capped as low as $3,333 due to CGDP payments included in patient OOP accumulation.
- **Expanded LIS.** Full LIS benefits will be available for individuals up to 150% of FPL

2025 and beyond

- **Permanent OOP Cap.** Enrollee OOP costs are capped at $2000 annually, to be adjusted for inflation
- **Elimination of Coverage Gap.** The coverage gap phase is eliminated entirely, compressing the Part D benefit into three phases instead of four: (1) deductible, (2) initial coverage phase, and (3) catastrophic coverage phase
- **Restructuring of Liabilities.** Liability throughout the benefit shifts to fall primarily on Part D plans, and secondarily on manufacturers—the government retains a small share of liability in the catastrophic phase, while the enrollee's share is capped
- **Monthly OOP Cap.** Enrollees have option to elect that their OOP costs be "smoothed" throughout the plan year
- **Phased-in Manufacturer Discount.** For LIS beneficiaries or "specified small manufacturers", the mandatory manufacturer discount will be phased in over the course of several years (2025-2031)
- **Changes to TrOOP.** Mandatory manufacturer discounts no longer count to helping the enrollee progress through the Part D benefit. Supplemental benefits accrue to TrOOP.

OOP = out of pocket; LIS = low-income subsidy; FPL = federal poverty level; TrOOP = true out of pocket

IRA's Major Part D Benefit Changes Take Effect in 2025



Source: Manatt graphic

Medicare Part D Prescription Payment Plan

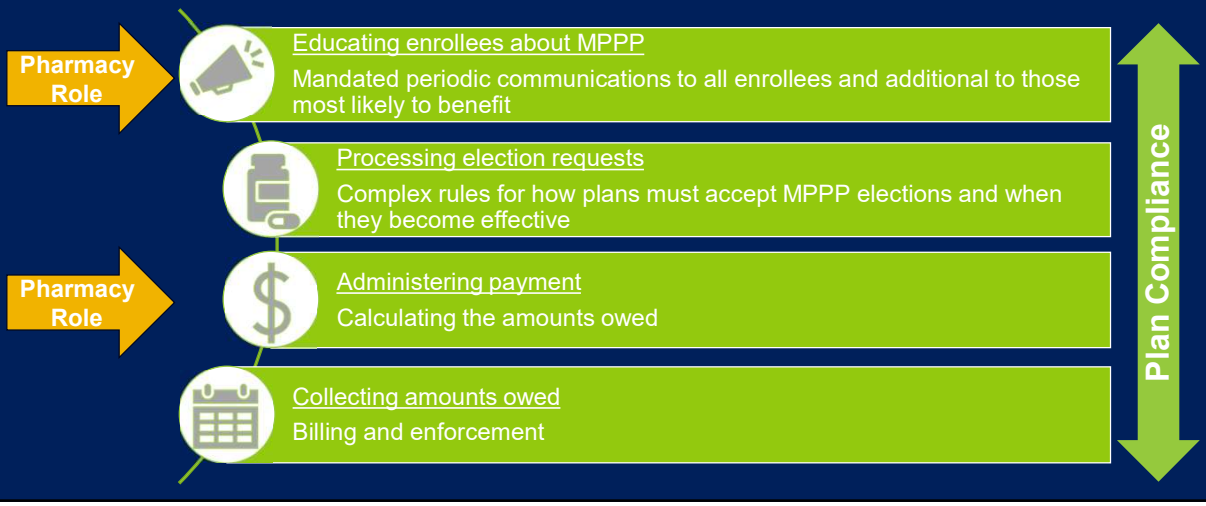
MPPP Allows Patients to "Smooth" Part D costs

Patients can divide the OOP cost of Part D drugs over the remaining months of the year, rather than pay at the pharmacy counter

- Passed under the IRA, takes effect January 1, 2025.
- Optional program - Part D enrollees elect to opt in.
- For enrollees who elect in, PDP sponsor pays pharmacy OOP cost; later bills enrollee up to maximum monthly amount.

Main Areas of Compliance

Plans must consider the following four areas to ensure compliance with MPPP guidance.



Educating Enrollees: General Outreach and Education

PDP Sponsors must educate all enrollees about MPPP.

CMS has developed template communications and educational materials. Plans may use CMS materials or, in some cases, develop their own materials if they ensure accuracy.

CMS recommends using template fact sheet it has developed.

- **ID Card Mailing:** Must include info on MPPP and an election form (or in separate mailing at same time).
- **Evidence of Coverage, Annual Notice of Change and Explanation of Benefits**: Templates updated by CMS to contain information about MPPP.
- **Part D Sponsor Websites**: Must contain information about MPPP and election mechanism. CMS specifies 10 areas of content including "overview of program" and how to opt in and out.

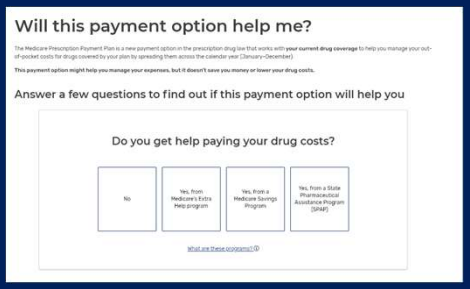
Medicare Prescription Payment Plan Final Part Two Guidance (cms.gov). Available at: https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-two-guidance.pdf

Educating Enrollees: General Outreach and Education

Medicare.Gov contains information on MPPP

Promotional video

"Will this payment option help me?" wizard



www.medicare.gov

Educating Enrollees: Targeted Outreach

Enrollees "likely to benefit" from MPPP must have specific notice of the program directed to them by plan.

Prior to Plan Year

- Identify all enrollees with OOP costs above $2,000 through September.
- Send standard "Medicare Prescription Payment Plan Likely to Benefit Notice" and educational materials by mail or electronically.
- Must send by December 7 but CMS encourages in October, November, or early December 2024.

During Plan Year

- Actively monitor pharmacy claims (but not UM requests). A claim/request **at or above $600** single prescription OOP threshold triggers notices except at end of year.
- Part D plan must send "Likely to Benefit Notice" and educational materials.
- Notify pharmacy, which must also provide notice to enrollee (next slide).

Medicare Prescription Payment Plan Final Part One Guidance_0.pdf (cms.gov), Available at: https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf
Medicare Prescription Payment Plan Final Part Two Guidance_Final.pdf (cms.gov). Available at: https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-two-guidance.pdf

Educating Enrollees: Targeted Outreach

Pharmacies must notify enrollees they are "likely to benefit" from MPPP

Plans use NCPDP Approved Message Codes to indicate to pharmacy that enrollee is likely to benefit from MPPP

3.3 What is the hierarchy for returning Medicare Prescription Payment Plan Approved Message Code (548-6F) values:

- 056: Beneficiary likely to benefit from Medicare Prescription Payment Plan
- 057: Beneficiary participating in Medicare Prescription Payment Plan
- 058: Beneficiary no longer participating/has opted not to participate in Medicare Prescription Payment Plan

Enrollee notification obligations by pharmacy type:

Retail: Provide hard copy of "Medicare Prescription Payment Plan Likely to Benefit Notice" at Rx pickup. Can additionally use portal/electronic.

Long Term Care: Provide hard copy of "Medicare Prescription Payment Plan Likely to Benefit Notice" at time of billing.

Other (Mail Order): Convey content of Notice via telephone, using existing touchpoints. Do not delay dispensing.

https://ncpdp.org/NCPDP/media/pdf/NCPDP_WG9_Medicare_PartD_FAQ.pdf, https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-two-guidance.pdf

Processing Election Requests

Plans must accept enrollees' elections into the MPPP and terminations from the program and quickly make them effective. They must accept paper, telephone and website elections.

Effective Date of Election

- **Prior to Plan Year**
  - Election takes effect at beginning of plan year.s
- **During Plan Year**
  - Election must take effect within 24 hours.
  - In some cases, must be retroactive with retroactive reimbursement :
    - Effective back to 24 hours after request, if not processed timely.
    - For urgently needed drugs, if the election is requested within 72 hours.
    - Retroactive refund of excess payments for low-income subsidy.

No requirement for pharmacies to facilitate elections for 2025

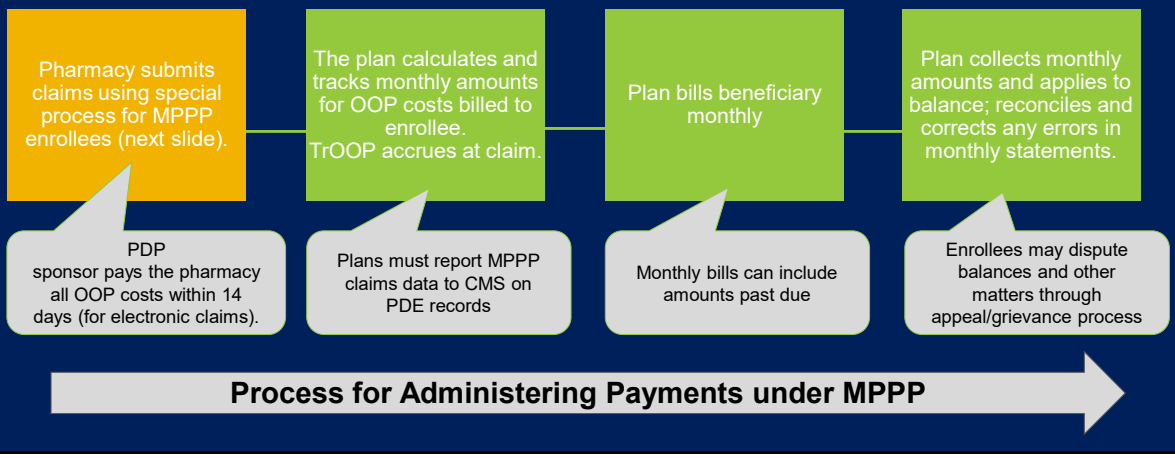
Plans must transmit election info to CMS using "MARx" enrollment system

CMS guidance has complex rules and template documents for accepting, processing and documenting elections/terminations.

Medicare Prescription Payment Plan Final Part One Guidance_0.pdf (cms.gov). Available at: https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf

Administering Payment

After election into the MPPP, the enrollee pays nothing at pharmacy counter.



Administering Payment

Pharmacies must process claims correctly to generate MPPP cost sharing. To facilitate claims, each PDP Sponsor creates second BIN/PCN for MPPP

- PDP Sponsors create new Bank Identification Number (BIN) and/or Processor Control Number (PCN) for MPPP claims
  - Sponsors will transmit this info to pharmacies and CMS will make a list public
- Primary unique BIN/PCN used for the initial Part D claim adjudication
  - This first adjudication is used for COB purposes and calculating TrOOP etc.
- Second MPPP BIN/PCN used to determine patient OOP
  - If there is other health insurance, pharmacy submits claim there before using this second MPPP BIN/PCN
- Readjudicate claims when enrollee joins MPPP.
  - No requirement to resubmit for retroactive MPPP elections

Medicare Prescription Payment Plan Final Part One Guidance_0.pdf (cms.gov), Medicare Prescription Payment Plan Final Part Two Guidance_Final.pdf (cms.gov)

Administering Payment: Monthly Payment Formula

Patients pay the plan monthly the lesser of their actual incurred costs, or a monthly maximum payment.

First Month Maximum:	Subsequent Months' Maximum:
$\frac{\text{(OOP Maximum – Costs incurred pre-election)}}{\text{Months remaining in the year}}$	$\frac{\text{(Costs carried over from prior + new costs)}}{\text{Months remaining in the year}}$

Inflation Reduction Act Section 11202; Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans: Draft Part One Guidance on Select Topics, Implementation of Section 1860D-2 of the Social Security Act for 2025, and Solicitation of Comments (https://www.cms.gov/files/document/medicare-prescription-payment-plan-part-1-guidance.pdf)

Sample Scenario

Month	OOP Costs Incurred	Maximum Monthly Cap	Monthly Payment Due	Remaining OOP Cost Carried Over
January	$10	$166.67 ($2000/12) (Special calc in 1st month)	$10 (OOP is below cap)	-
February	-	-	-	-
March	$10	$1 ($10/10)	$1	$9
April	-	$1 ($9/9)	$1	$8
May	-	$1 ($8/8)	$1	$7
June	-	$1 ($7/7)	$1	$6
July	-	$1 ($6/6)	$1	$5
August	$1980	$397 (($5 + 1980)/5)	$397	$1588
September	-	$397 ($1588/4)	$397	$1,191
October	-	$397 ($1191/3)	$397	$794
November	-	$397 ($794/2)	$397	$397
December	-	$397 ($397/1)	$397	-
Total	**$2000**		**$2000**	

Patient Fills Generic

Patient Fills Generic

Patient Fills Brand Specialty

See slide notes for assumptions and narrative

Worksheet

Polling Question #1

Patient Electing MPPP Option before plan year, First/only fill is $1000 oop in January. What is the MPPP payment for January?

a) $1000.00
b) $166.67
c) $120.00
d) $83.34

Polling Question #2

Patient Electing MPPP Option before plan year, First/only fill is $1000 oop in January. What is the MPPP payment for February?

a) $833.33
b) $166.67
c) $75.76
d) $83.33

Polling Question #3

Patient Electing MPPP Option before plan year, First/only fill is $1000 oop in February. What is the MPPP payment for February?

a) $181.82
b) $166.67
c) $90.91
d) $83.34

Polling Question #4

Patient Electing MPPP Option before plan year, First/only fill is $1000 oop in December. What is the MPPP payment for December?

a) $2000
b) $1000
c) $166.67
d) $83.34

Collecting Amounts Owed

PDP sponsors send monthly bills to enrollees and collect OOP costs in monthly installments. Plans are encouraged to set up EFT or payment by check.

There is Limited Flexibility for Collections:

- Cannot bill more than monthly maximum amount.
- No fees or interest for late payments.
- Amounts collected are first applied to premium, then MPPP balances.
- Collection efforts must follow state and federal law.
- The plan can terminate MPPP election for failure to pay but:
  - Enrollees get 2-month grace period.
  - Must reinstate enrollees who failed to pay for "good cause."
  - May reinstate all others who come current.
  - Must allow re-election in subsequent year if the balance is current.
  - Cannot disenroll from plan for delinquency.

The strict rules limiting collection efforts may mean plans may incur significant losses from uncollected balances. Plans must bear these losses but can account for them in bids (OACT has published specific guidance).

Benefits and Pitfalls of MPPP

Benefits	Potential Problems

• **Enrollees**
  • Enrollees pay $0 at Point of Sale for covered Part D drugs
  • Can pay OOP costs in lower monthly installments
  • Flexibility to enter or leave program voluntarily
• **Plans**
  • Program may increase enrollee satisfaction with plan and its benefit design
• **Pharmacies**
  • Program increases likelihood of patients filling prescriptions
	• **Enrollees**
	  • Not aware of the costs of drugs they eventually must pay
	  • Monthly formula is confusing
	  • Prescriptions filled later in the year have fewer months left to pay off
	• **Plans**
	  • Little recourse to collect unpaid balances
	  • Must bear administrative costs of running program
	• **Pharmacies**
	  • Potential for patient confusion
	  • Administrative burden of notifying patients likely to benefit and claims processing

Questions

Break

Update on PBM Reform

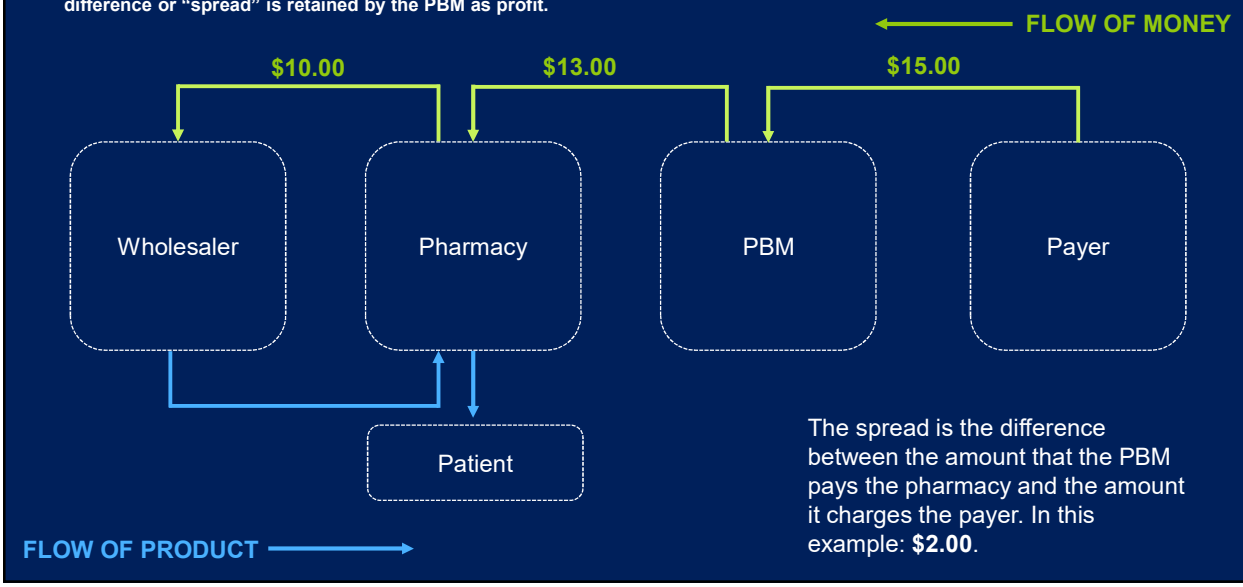
Agenda

- Key Terms in PBM Reforms
- Current State of Play in Congress
- Recent Developments
- Efforts to define PBM
- Q&A and Workshop

Key Terms in PBM Reform

Spread Pricing

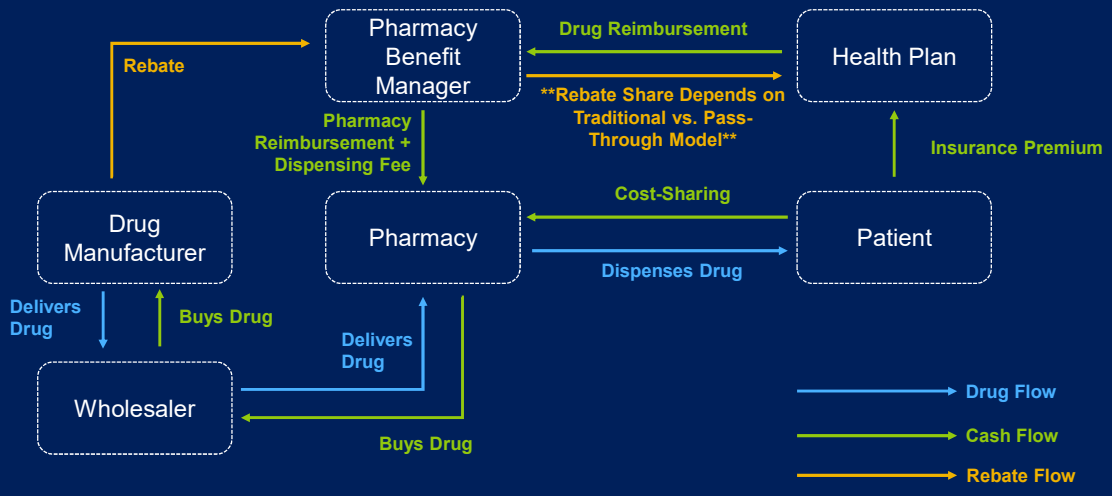
Spread pricing is a payment model in which a payer agrees to pay a set reimbursement for each drug to a PBM, regardless of the pharmacy chosen. If what the pharmacy charges the PBM is more than the agreed upon rate, this difference or "spread" is retained by the PBM as profit.



The spread is the difference between the amount that the PBM pays the pharmacy and the amount it charges the payer. In this example: **$2.00**.

Rebate Pass-Through Contracting Option

Rebate pass-through may refer either to a payment model where all manufacturer rebates negotiated by a PBM are passed through to a client/plan sponsor, or may refer to a payment model where all rebates are passed through to the consumer at the point-of-sale.

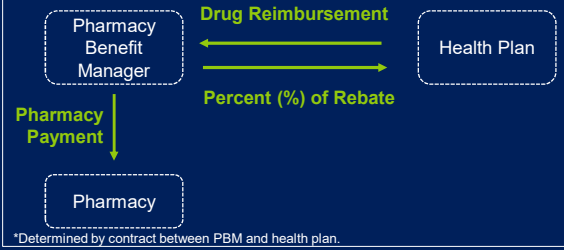


PBM Delinking

Delinking refers to the concept of removing any direct connection between the compensation a PBM receives and the price of a drug (for example, eliminating price-based rebates).

Current Model

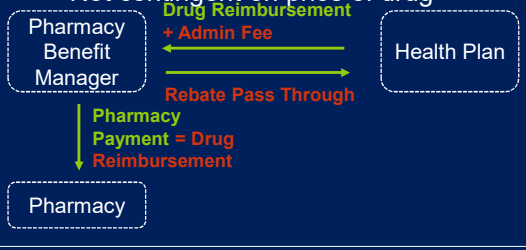
- PBM may receive compensation from:*
  - Percentage of rebates received
  - Spread pricing
  - Admin fees based on price of drug



*Determined by contract between PBM and health plan.

Model Post-Delinking

- PBM may only receive compensation from bona fide service fees
  - Flat
  - Fair market value
  - Not contingent on price of drug



Anti-Steering

Anti-steering legislation refers to proposals that would prohibit a PBM from compensating a network pharmacy less than affiliated pharmacies.

Anti-steering legislation refers to proposals that would prohibit a PBM from compensating a network pharmacy less than affiliated pharmacies

PBM Administrative Fees

Fees Paid By Manufacturers

- Negotiating and administering data use agreements
- Adherence and patient clinical support programs (preferred brand drugs)
- REMS administration
- Operate patient HUBs and call centers
- Medical education programs
- Clinical and observational studies

Fees Paid by Plan Sponsors

- Formulary management
- Pharmacy network management
- Disease management programs
- Adherence programs – broadly across all drugs
- Drug utilization reviews
- Claims administration
- Enrollee support services

Current State of Play in Congress

Most PBM Reform Falls in Two Buckets

Transparency Provisions

Regulation of Practices

Federal Legislation: Snapshot of PBM Reform Bills

H.R. 5378: Lower Costs, More Transparency Act

Last Major Action: Passed House 32-71 in December 2023

S. 2973: Modernizing and Ensuring PBM Accountability (MEPA) Act

Last Major Action: Senate Finance approved 26-0 in December 2023

H.R. 2880: Protecting Patients Against PBM Abuses Act

Last Major Action: E&C Advanced 46-0 in December 2023

S. 1339: Pharmacy Benefit Manager Reform Act

Last Major Action: Senate HELP approved in May 2023 without objection

H.R. 6283: Delinking Revenue from Unfair Gouging (DRUG) Act

Last Major Action: E&W Advanced 29-11 in February 2024

Common Proposals in Federal PBM Legislation

- **Reporting**: Increasing PBM reporting to plan sponsors and the Federal government.
- **Anti-Spread Pricing**: PBMs would not charge an amount for a drug's ingredient cost or dispensing fee that is different from the amount reimbursed
- **Rebate Pass-Through**: PBMs would pass on 100 percent of rebates, fees, alternative discounts, and other remuneration to plan sponsors.
- **Delinking**. PBMs could be limited to charging administrative fees that are flat and fee-based, determined to be "reasonable", or delinked from the cost of a drug.
- **Anti-Steering**. PBMs would be prohibited from compensating a network pharmacy less than affiliated pharmacies.

A Review: Policy Areas of Overlap Across Legislation

	H.R. 5378 Lower Costs, More Transparency	H.R. 2880: Protecting Patients Against PBM Abuses Act	S. 2973: Modernizing and Ensuring PBM	S. 1339: Pharmacy Benefit Manager Reform Act	H.R. 6283: DRUG Act
Delinking		Part D	Part D		Commercial
Spread Pricing Ban	Medicaid	Medicare	Medicaid	All markets	Commercial
Rebate Pass-Through	Medicaid and certain drugs for private health plans and employers	Medicaid, with some exceptions	Medicaid	Private Health Plans and Employers	Commercial
PBM Pricing and Fee Transparency to Plans/Sponsors	Commercial	Part D	Part D	Commercial	
Anti-steering	Prohibits gag clauses	Prohibited	Mandates study of vertical integration	Increases oversight of affiliated entities	
Pharmacy DIR Limitations	All Markets	Part D reporting	Part D		

Other Proposals In Legislation

Provision	Description	Bills Included
PDP Sponsor Audit Rights	PDP Sponsor Audit Rights Grants PDP sponsor the right to an annual audit (auditor selected by the PBP sponsor), including information on affiliates	HR 5385, S 2973
GAO Report on PBM Reporting to PDP Sponsors	Directs GAO to conduct a study and report to Congress on the enhanced PBM reporting requirements, including overlap with other state and Federal reporting requirements.	HR 5385, S 2973
Standardized Pharmacy Performance Measures	Requires PDP sponsors to utilized on pharmacy performance measures (1) established and adopted by the Secretary; and (2) relevant to the pharmacy type. pharmacy arrangements.	HR 5393, S 2973

Other Proposals In Legislation (cont.)

Provision	Description	Bills Included
PDP Reporting to Pharmacies on Drug Claims	Requires PDP sponsors to furnish the following information to a dispensing pharmacy upon furnishing a claim: Network Reimbursement ID, fees, pharmacy price concessions, discounts, incentives, and any forms of remuneration that affect payment.	HR 5393, S 2973
P&T Committee Conflict of Interest	Clarifies that independent experts on P&T committees must be free of any conflict with respect to the PBM.	HR 2880, S 2973
Mid-Year Formulary Changes for Biosimilars	Allows negative mid-year formulary changes to reference biologics when a PDP sponsors adds a biosimilar at the same or higher preferred status, or to the same or lower cost sharing tier.	HR 5372, S 2973

Workshop

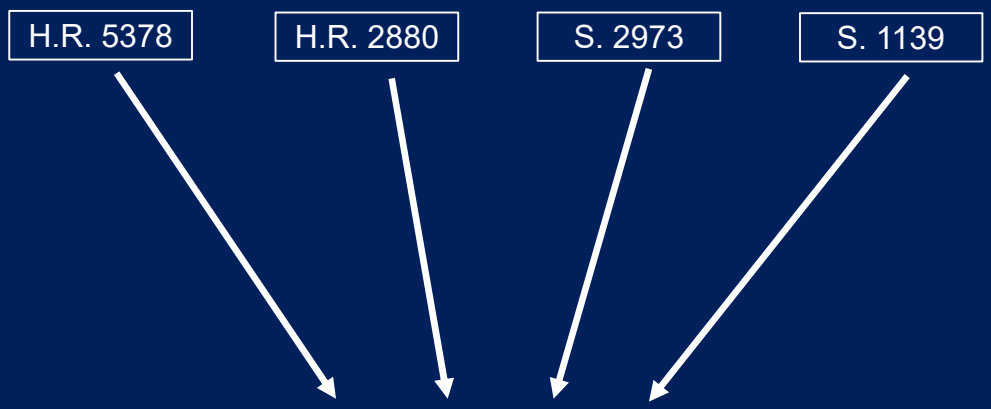
Instructions

- At your table, discuss and determine the **potential impact** of PBM transparency, or delinking proposals per the industry
  - PBM
  - Plan
  - Manufacturer
  - Pharmacy
- **ODD** numbered tables – **PBM Transparency**
- **EVEN** numbered tables – **PBM Delinking**
- Assign one "**scribe**" per table to submit answers via polling prompt
- Be prepared to also "report out" from the table

Discussion

Recent Developments

Could 2024 end the same way in which 2023 ended?

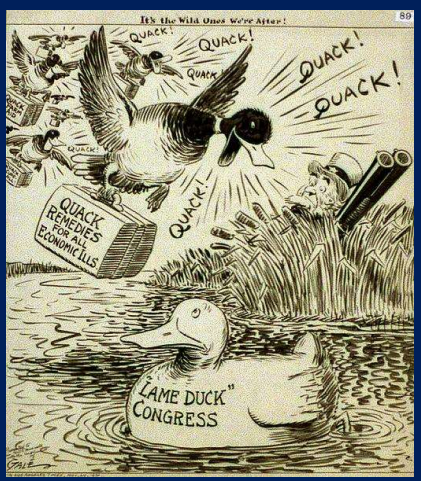


Congress Failed to Include Health Package in FY24 Spending

- Disagreements over details of the emerging health care package prevented its inclusion in the FY24 spending deal
  - 10 committees involved in completing package
- Leadership desire to avoid “omnibus package” contributed to failure
  - A combined package that could includes multiple spending bills, and some policy provisions.
- How/when does Congress pass a PBM reform package?

How/When Does Congress Pass PBM Reform Package?

- Lame Duck: Congressional session taking place after the November election
  - The furthest point from the next election, with many members retiring.
  - Votes are not as “hard” and consensus is easier to attain as Congress ties up loose ends.
  - Congress historically more productive during lame duck sessions.



Questions

Disclaimer

All Faculty in this education session have obtained the appropriate permission to use copyright materials.

Sources of all images are provided in citations.

FACULTY BIOGRAPHY

Adam Finkelstein, JD, MPH **Counsel** **Manatt, Phelps & Phillips LLP**	With a practice focused on the intersection of managed care, federal health care programs and healthcare innovation, Adam guides health plans and other stakeholders on emerging developments and complex regulatory matters in the Medicare Advantage, Part D and Medicaid managed care programs. In addition, he is a recognized thought leader and "go to" resource on and delivery system transformation initiatives in the Medicare and Medicaid programs and innovations in insurance benefit design. Prior to joining Manatt, Adam served in the CMS Center for Medicare and Medicaid Innovation. In that role, he launched and led the Medicare Advantage Value-Based Insurance Design model test—an innovative test of benefit flexibilities for Medicare Advantage and Medicare Part D enrollees. Adam has also been in-house counsel for one of the country's largest national insurers, supporting its Medicaid and CHIP business lines. He held lead legal responsibility for the company's Medicaid managed care provider relationships, helped launch Medicare-Medicaid plans, and guided new proposals to state Medicaid agencies. Adam serves as an appointee to the Montgomery County, MD Commission on Health.
Ross D. Margulies, JD, MPH **Partner** **Manatt, Phelps & Phillips, LLP**	Ross Margulies is a Partner with Manatt Health who helps clients navigate health care's most complex legal, regulatory and legislative matters. Ross focuses his practice on supporting clients with complex federal and state legal and regulatory issues across the life sciences and broader health care industries, with a particular emphasis on Medicare and Medicaid law. Offering coverage and coding advice, compliance counseling, legislative and policy strategy and market access consulting, Ross works with biopharmaceutical companies, medical device manufacturers, digital health companies, providers, payers and other innovators seeking counsel on novel coverage, coding, reimbursement and compliance matters. He also has significant experience navigating the 340B Drug Pricing Program and the Medicare Drug Price Negotiation Program of the Inflation Reduction Act. Previously, Ross served in roles at the Office of the General Counsel at the U.S. Department of Health and Human Services and at the Health Resources and Services Administration, as well as serving as a Health Policy Fellow in the office of Vermont Senator Bernie Sanders. In addition to his work at Manatt, Ross provides regular pro bono advice to health care organizations servicing disadvantaged populations and teaches Medicare and Medicaid Law at Vanderbilt Law School.