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Transparency in Drug Pricing Developments –

State and Federal Policy and Legislative Initiatives

Speakers

Tara Dwyer

Member | Mintz

TEDwyer@mintz.com

Xavier Hardy

Associate | Mintz

XGHardy@mintz.com

Bridgette Keller

Associate | Mintz

BAKeller@mintz.com

Agenda

- What is happening in Washington, DC?
- How is CMS trying to impact Part D member cost shares?
- How are states addressing pharmacy pricing matters?

What is the “drug pricing” problem that everyone is trying to fix?

There is no one answer and opinions vary greatly!

- **Frequent answers include:**
  - Drugs cost too much
  - Drugs are more expensive in the US than they are in other countries
  - PBMs are middlemen that keep drug rebates
  - Rebates do not help members at the point-of-sale
  - Pharmacies do not understand what they are being paid
  - Plan members do not understand their plan designs

- **Answers often depend on or impact who the answerer blames for the problem.**
  - Manufacturers, Wholesalers, Pharmacies, PBMs, Plans

What solutions are governments considering?

- Many different types of legislation and regulations coming from different governmental bodies
- Why?
  - Multiple issues to address
  - Nature of American Health Care System
    - Federal health care programs
    - Individual market
    - Employer market – insured and self-funded
    - Cash-paying

What is happening in Washington, DC?

Infrastructure Investment and Jobs Act – November 2021

SEC. 90006. MORATORIUM ON IMPLEMENTATION OF RULE RELATING TO ELIMINATING THE ANTI-KICKBACK STATUTE SAFE HARBOR PROTECTION FOR PRESCRIPTION DRUG REBATES.

Notwithstanding any other provision of law, the Secretary of Health and Human Services shall not, prior to January 1, 2026, implement, administer, or enforce the provisions of the final rule published by the Office of the Inspector General of the Department of Health and Human Services on November 30, 2020, and titled "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees" (85 Fed. Reg. 76666).

Build Back Better Act

- Drug Pricing Provisions
  - HHS direct negotiation with manufacturer for limited number of Medicare B and D drugs without generic competition
    - Initially 10 (2025), 15 (2026), and 20 (2028+)
    - Key exemptions
      - (1) New drugs and biologics for 9 and 13 years, respectively, (2) orphan drugs, (3) in 2021, less than $200M Medicare spending
  - Inflation rebates for Medicare and private insurance
  - Eliminates the Trump rebate rule
- Plan Member Provisions
  - Establish a Medicare Part D MOOP
  - Limit cost shares for 30 days of insulin at $35 for Medicare and private insurance

The New York Times

Manchin Pulls Support From Biden's Social Policy Bill, Imperiling Its Passage

The West Virginia senator's comments dealt a potentially fatal blow to the centerpiece of the president's domestic agenda, and drew a broadside from the White House.

By Emily Cochrane and Catie Edmondson

Published Dec. 19, 2021 Updated Dec. 20, 2021

Now?

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Congress of the United States
Washington, DC 20515

January 31, 2022

The Honorable Charles Schumer
Senate Majority Leader
United States Senate
Washington, D.C. 20510

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
Washington, D.C. 20515

Dear Leader Schumer and Speaker Pelosi,

We write today urging you to take legislative action as swiftly as possible to lower drug prices. For years, people have sent us to Washington on the promise that we end Big Pharma's monopoly control over prices and provide patients with much needed relief. We must make good on that promise – and we have the ability to do so.

HEALTH NEWS ✓ Fact Checked

Biden's State of the Union: Drug Pricing, Mental Health Care, and his 'Test to Treat' COVID Plan

Written by Shawn Radcliffe on March 2, 2022 — Fact checked by Jennifer Chesak

POLITICO

Manchin floats drug pricing in new counteroffer

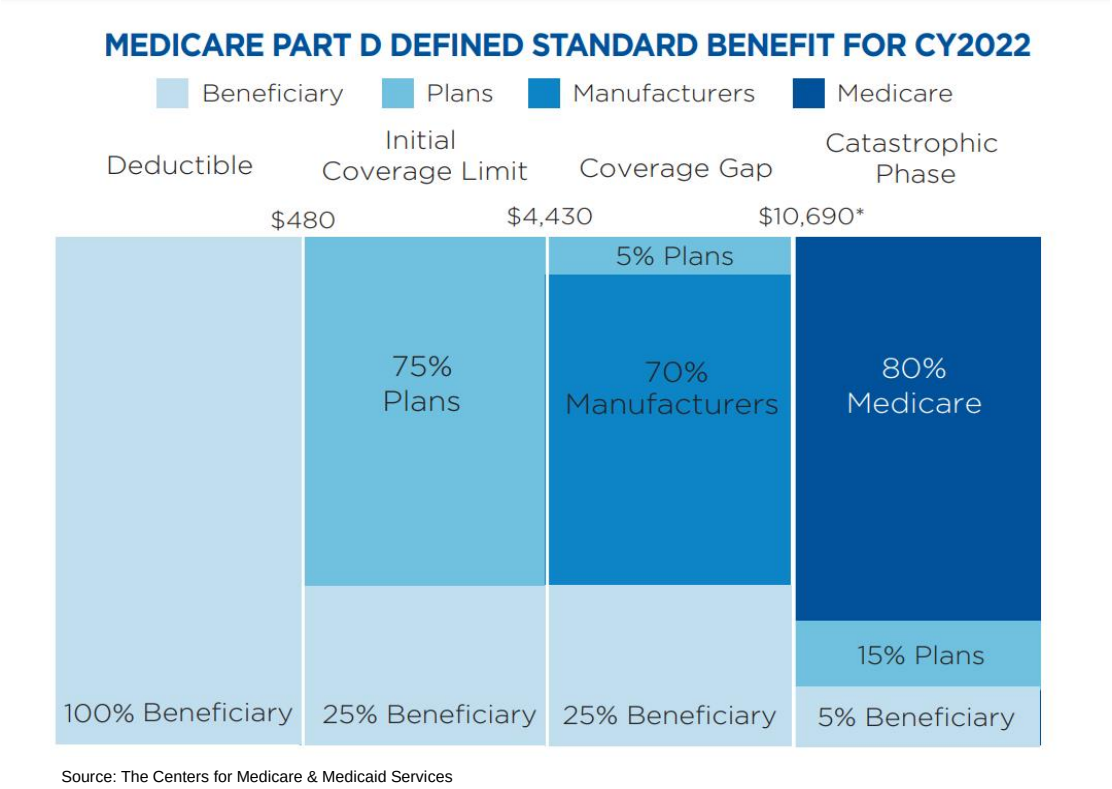
By **LAUREN GARDNER, DAVID LIM** and **KATHERINE ELLEN FOLEY** | 03/04/2022 12:00 PM EST

How is CMS trying to impact Part D member cost shares?

Medicare Part D

Medicare Prescription Drug Coverage

- Medicare prescription drug coverage through private insurers
- Part D plans (or their PBMs) establish pharmacy network and negotiate rebates with pharmaceutical manufacturers
- Part D plans receive partially capitated payment on a monthly basis based on estimated cost in annual bids
- Plans must adhere to Medicare requirements, including:
  - Must offer a legislatively specified “standard” package of benefits or alternative coverage that is actuarially equivalent to a standard plan
  - Limits on cost sharing and coverage of “6 protected Classes”
- Wide variation of benefit design, specific drugs included in formularies, cost sharing for particular drugs, or the level of monthly premiums



Source: The Centers for Medicare & Medicaid Services

Medicare Part D

Post Point-of-Sale Compensation

- Price a beneficiary pays at the pharmacy (i.e. point-of-sale, or "POS") is not the price the Part D plan ultimately pays for a covered drugs
- Post-POS compensation must be reported annually as **Direct and Indirect Remuneration (DIR)**
  - Impacts calculation of Medicare payment to Part D plans
  - DIR includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, upfront payments, coupons, goods in kind, free or reduced-price services, grants, or **other price concessions** or similar benefits from manufacturers, pharmacies or similar entity

- **Pharmacy Price Concessions. Arrangement where pharmacy pays sponsor a certain amount post-POS because of the pharmacy's failure to meet certain performance measures.**
- **Non-Pharmacy Price Concessions. Legal settlement amounts and risk sharing adjustments.**
- **Manufacturer Rebates. Discounts paid by drug manufacturers after a prescription is dispensed to plans or PBMs.**

Medicare Part D

Price Concessions

"**Negotiated Prices**"

- Beneficiary cost sharing determined based on each sponsor's "negotiated prices" for a drug
- Reported monthly to CMS as part of Prescription Drug Event (PDE) submissions
- Defined as price paid to a pharmacy at the point-of-sale for a covered drug dispensed to a plan beneficiary, inclusive of all:
  - Rebates
  - Dispensing fees
  - Pharmacy incentive payments (sponsor pays a pharmacy post-POS for meeting certain performance measures or having "high performance")
  - **Pharmacy price concessions**
- "Reasonably Determined" Exception - Pharmacy price concessions and incentive payments that cannot reasonably be determined at the point-of-sale excluded from calculation of "Negotiated Prices"

CMS concerns over Reporting of "Negotiated Prices"

- Significant growth in reported price concessions over last 10 years
  - DIR data shows pharmacy price concessions grew more than 107,400% between 2010 and 2020
    - $8.9 million in 2010
    - $9.5 billion in 2020
  - Growth arguably caused by creation of "Reasonably Determined" exception in 2014
- "Reasonably Determined" exception was intended to be narrow exception, but instead allowed for all performance-based pharmacy payment adjustments to be excluded from the "negotiated prices"
- Whether Part D plan sponsors include price concessions in the "negotiated prices" impacts where benefits of price concession accrue

2023 Medicare Advantage and Part D Proposed Rule

- ***Negotiated price*** means the price for a covered Part D drug that—

  (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug;

  (2) Meets all of the following:

  (i) Includes all price concessions…from network pharmacies or other network providers;

  (ii) Includes any dispensing fees; and

  (iii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices; and

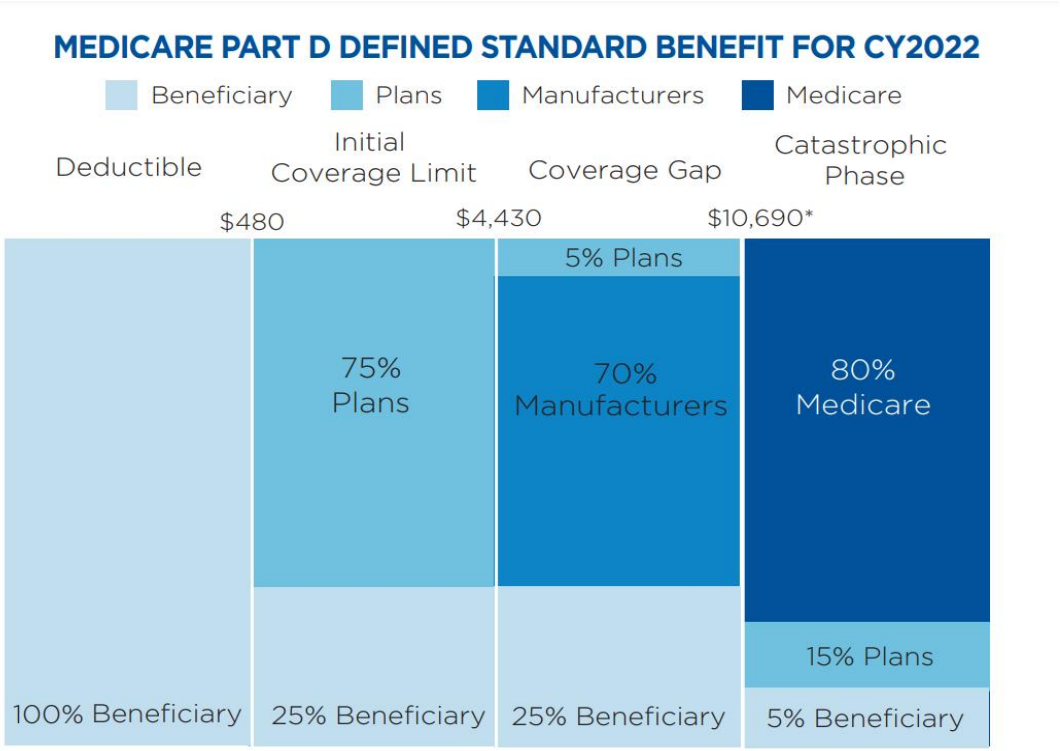
  (3) Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor passes through to Part D enrollees at the point of sale.

- Would require Part D plan sponsors to report to CMS the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with a Part D sponsor or its intermediary
- Eliminates “Reasonably Determined” Exception
- Also defines ***Price concession*** as “any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.”

Medicare Part D

Senior Savings Model

- Authorized under Section 3021 of the Affordable Care Act
- Demonstration project that will allow participating Part D plans to offer a broad set of formulary insulins as a Supplemental Benefit
- Caps a beneficiary's monthly copayment at $35 (per month's supply) through the deductible, initial coverage, and coverage gap phases of the Part D coverage
  - Participating pharmaceutical manufacturers will pay the 70% discount in the coverage gap for the Part D insulins they market
  - Manufacturer discount payments would now be calculated before the application of Supplemental Benefits under the Model
  - CY 2022/2023 Manufacturers (Eli Lilly, MannKind Corporation, Mylan, Novo Nordisk, Sanofi-Aventis)
- Model runs from CY 2021 through CY 2025



Source: The Centers for Medicare & Medicaid Services

Medicare Part D

Recent Changes to Specialty Tiering

- Medicare regulations limit beneficiary cost-sharing
- Specialty Tier
  - Prescription drug plans can charge higher co-insurance for drugs above specialty tier threshold (for CY 2022, $830)
  - Co-insurance in specialty tier allowed up to 25% or 33%, depending on the plan's deductible
- Beginning with CY 2022
  - Plans are allowed to allocate drugs across two specialty tiers rather than one
  - Preferred vs. Non-preferred Specialty Tier
  - Changes to methodology for determining whether a drug meets specialty tier cost threshold
    - From "negotiated price" to "ingredient cost"

How are states addressing pharmacy pricing matters?

State Legislative Initiatives

- Variety of approaches:
  - Regulating PBM practices
    - Patient Price Transparency
    - Pharmacy price transparency and appeal rights
    - Adjustments after point-of-sale
    - Patient copayments

Rutledge v. PCMA

- Arkansas Act 900 requires PBMs to:
  - Reimburse pharmacies for generic drugs at a price equal to or higher than the pharmacies' cost for the drug;
  - Update their MAC lists at least seven days after a certain increase in acquisition costs;
  - Follow certain administrative appeals procedures;
  - Allow pharmacies to reverse and re-bill each claim when a pharmacist cannot procure a drug at a cost that is equal to or less than the MAC price; and
  - Allow pharmacies to decline to dispense a drug if the reimbursement rate is lower than the pharmacy's acquisition cost.
- PCMA challenged the Arkansas statute, arguing that it was preempted by ERISA.
- SCOTUS held that ERISA does not preempt this law, which only regulates reimbursement levels paid by PBMs to pharmacies

PCMA v. Webhi

- North Dakota law regulates, among other things, (i) pharmacy reimbursements and fees; (ii) network coverage, composition and design; and (iii) patient disclosures.
  - PBM may not directly or indirectly charge or hold a pharmacy responsible for a fee related to a claim: (a) That is not apparent at the time of claim processing; (b) That is not reported on the remittance advice of an adjudicated claim; or (c) After the initial claim is adjudicated at the point of sale. § 19-02.1-16.1(2).
  - A pharmacy or pharmacist may provide relevant information to a patient if the patient is acquiring prescription drugs. This information may include the cost and clinical efficacy of a more affordable alternative drug if one is available. Gag orders of such a nature placed on a pharmacy or pharmacist are prohibited. § 19-02.1-16.1(7).
  - PBM may not require pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state. § 19-02.1-16.1(11).
  - If requested by a plan sponsor contracted payer, PBM that has an ownership interest, either directly or through an affiliate or subsidiary, in a pharmacy shall disclose to the plan sponsor contracted payer any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor contracted payer. § 19-02.1-16.2(2).
  - PBM and/or its affiliates or subsidiaries may not own or have an ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the pharmacy benefits manager, affiliate, or subsidiary agrees to not participate in a transaction that benefits the pharmacy benefits manager, affiliate, or subsidiary instead of another person owed a fiduciary duty. § 19-02.1-16.2(3).
- Eighth Circuit held that ERISA did not preempt the challenged provisions, but miscellaneous Medicare Part D standards preempt a handful of provisions *only as they apply to Medicare Part D plans*.

Patient Price Transparency

- Minn. Stat. Ann. § 62W.11

  (c) PBM must not prohibit a pharmacist or pharmacy from discussing information regarding the total cost for pharmacy services for a prescription drug, including the patient's co-payment amount and the pharmacy's own usual and customary price of the prescription.

  (d) PBM must not prohibit a pharmacist or pharmacy from discussing the availability of any therapeutically equivalent alternative prescription drugs or alternative methods for purchasing the prescription drug, including but not limited to paying out-of-pocket the pharmacy's usual and customary price when that amount is less expensive to the enrollee than the amount the enrollee is required to pay for the prescription drug under the enrollee's health plan.

Pharmacy Price Transparency and Appeal Rights

- Ariz. Rev. Stat.§ 20-3331.

A. A pharmacy benefit manager shall do all of the following:

1. Update the price and drug information for each list that the pharmacy benefit manager maintains every seven business days.
2. At the beginning of the term of a contract, on renewal of a contract and at least once annually during the term of a contract, make available to each network pharmacy the sources used to determine maximum allowable cost pricing.
3. Establish a process by which a network pharmacy may appeal its reimbursement for a drug subject to maximum allowable cost pricing.
4. Allow a pharmacy services administrative organization that is contracted with the pharmacy benefit manager to file an appeal of a drug on behalf of the organization's contracted pharmacies.

No Adjustments After Point-of-Sale

- Me. Rev. Stat. tit. 24-A, § 4317

  J. For a contract entered into or renewed on or after January 1, 2021, the contract may not contain a provision that purports to directly or indirectly charge the pharmacy provider or hold the pharmacy provider responsible for any fee related to a clean claim:

  1. That is not apparent at the time the carrier processes the claim;
  2. That is not reported on the remittance advice of a claim adjudicated by the carrier; or
  3. After the initial claim is adjudicated by the carrier.

Patient Copayments

- 18 Del. Code §3556A.

  (b) Application. This section applies to a carrier that provides coverage, either directly or through a pharmacy benefits manager, for prescription drugs under a health insurance policy or contract that is issued or delivered in this State.

  (c) A carrier subject to this section may not impose a copayment or coinsurance requirement for a covered prescription drug that exceeds the lesser of one of the following:

  (1) The applicable copayment or coinsurance that would apply for the prescription drug in the absence of this section.

  (2) The amount an individual would pay for the prescription drug if the individual were paying the usual and customary price.

  (3) The contract price for the prescription drug.

Patient Copayments

- Ohio Rev. Code Ann. §3959.20.

  (B) No health plan issuer, PBM, or any other administrator shall require cost-sharing in an amount, or direct a pharmacy to collect cost-sharing in an amount, greater than the lesser of either of the following from an individual purchasing a prescription drug: (1) The amount an individual would pay for the drug if the drug were to be purchased without coverage under a health benefit plan; (2) The net reimbursement paid to the pharmacy for the prescription drug by the health plan issuer, pharmacy benefit manager, or administrator.


Questions?