DINSMORE

Current Issues in Drug Reimbursement

MAY 19, 2026

OHIO HOSPITAL ASSOCIATION

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Executive Summary, Bryan P. Murray

- Medicare Drug Price Negotiation Program (MDPNP)
- 340B Rebate Model
- Executive Orders on Lowering Prescription Drug Prices
- Key Takeaways

The Medicare Drug Price Negotiation Program (MDPNP) & The Maximum Fair Price (MFP)

Quick History: Medicare Drug Pricing Before the MDPNP

- Federal government was historically prohibited from negotiating drug prices in the Medicare Program.
- When Medicare Part D was created in 2003 the enacting statute included a last-ditch addition known as "The Non-Interference Clause."
- The Non-Interference Clause States:
    1. The Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and prescription drug plan sponsors; and
    2. The Secretary may not require a particular formulary or institute a price structure for the reimbursement of Medicare Part D drugs.
- The effect: all drug price negotiations were historically left between drug manufacturers and private insurers and private business.

Medicare Drug Pricing Before the MDPNP

Medicare Part	Type of Drug	Payment Determination	Eligible for Negotiation by Government?
Part A	Drugs administered during inpatient stay	Usually included in DRG bundled payment to facility	No
Part B	Physician-administered drugs in outpatient setting	If paid separately, then ASP plus 6%	No. Drug pricing reported quarterly to the government
Part D	Outpatient retail drugs (ex., pharmacy dispensed)	Paid for by PDP Plan at rate negotiated between Plan and dispensing provider	No

The Medicare Drug Price Negotiation Program: Price Negotiation

- Enacted as part of the 2022 Inflation Reduction Act, the MDPNP requires the Centers for Medicare & Medicaid Services (CMS) to negotiate a "Maximum Fair Price" for certain prescription drugs under the Mediare Program.

- CMS must negotiate drug prices for brand-name drugs (without generic equivalents) that account for the greatest Medicare Spending.

- Negotiated prices become effective as follows:
  - 2026: 10 Drugs (Part D only)
  - 2027: 15 Drugs (Part D only)
  - 2028: 15 Drugs (Part D and Part B)
  - 2029 and all years thereafter: 20 Drugs*

*By 2029, 60 drugs will be subject to MDPNP negotiation/payment.

The Medicare Drug Price Negotiation Program: Price Negotiation

- Selected drugs must be among the top 50 drugs with the highest level of Medicare spending over the most recent 12 month period.
- Drugs must have had FDA market approval for at least 7 years (or 11 years if a biologic).
- Orphan drugs, plasma-derived products, and drugs with less than $200M in annual Medicare spending are exempt from negotiation.
    - In 2025, Congress enacted the HR1 Budget Reconciliation Act which included expanded the orphan drug carve out. This resulted in more drugs being exempted and/or delayed from negotiation under the MDPNP.

The Medicare Drug Price Negotiation Program: Price Negotiation

- Penalties:
  - Manufacturers that do not comply with the MDPNP are subject to civil penalties.
  - If negotiations are not finalized in time, the manufacturer is subject to imposition of excise taxes unless the manufacturer withdraws their drug from coverage under Medicare and Medicaid.
- Interaction with other programs:
  - Manufacturers do not have to provide MFP refund where drug was bought at 340B discount price. Rather, must simply provide whichever price is lower.

The Medicare Drug Price Negotiation Program: Price Reimbursement

- **Reimbursement**: MDPNP sets the Maximum Fair Price (or "MFP") at which a drug may reimbursed by CMS and/or Medicare Part D. However, MFP operates as a ceiling. Part D Plans can still reimburse dispensers lower than the MFP.

- **Contracting**: In practice, dispensers will continue to participate in federal Medicare and negotiate network participation agreements with Medicare Advantage and Part D Drug Plan. These arrangements will have their own reimbursement frameworks with each capped at the MFP for MDPNP drugs.

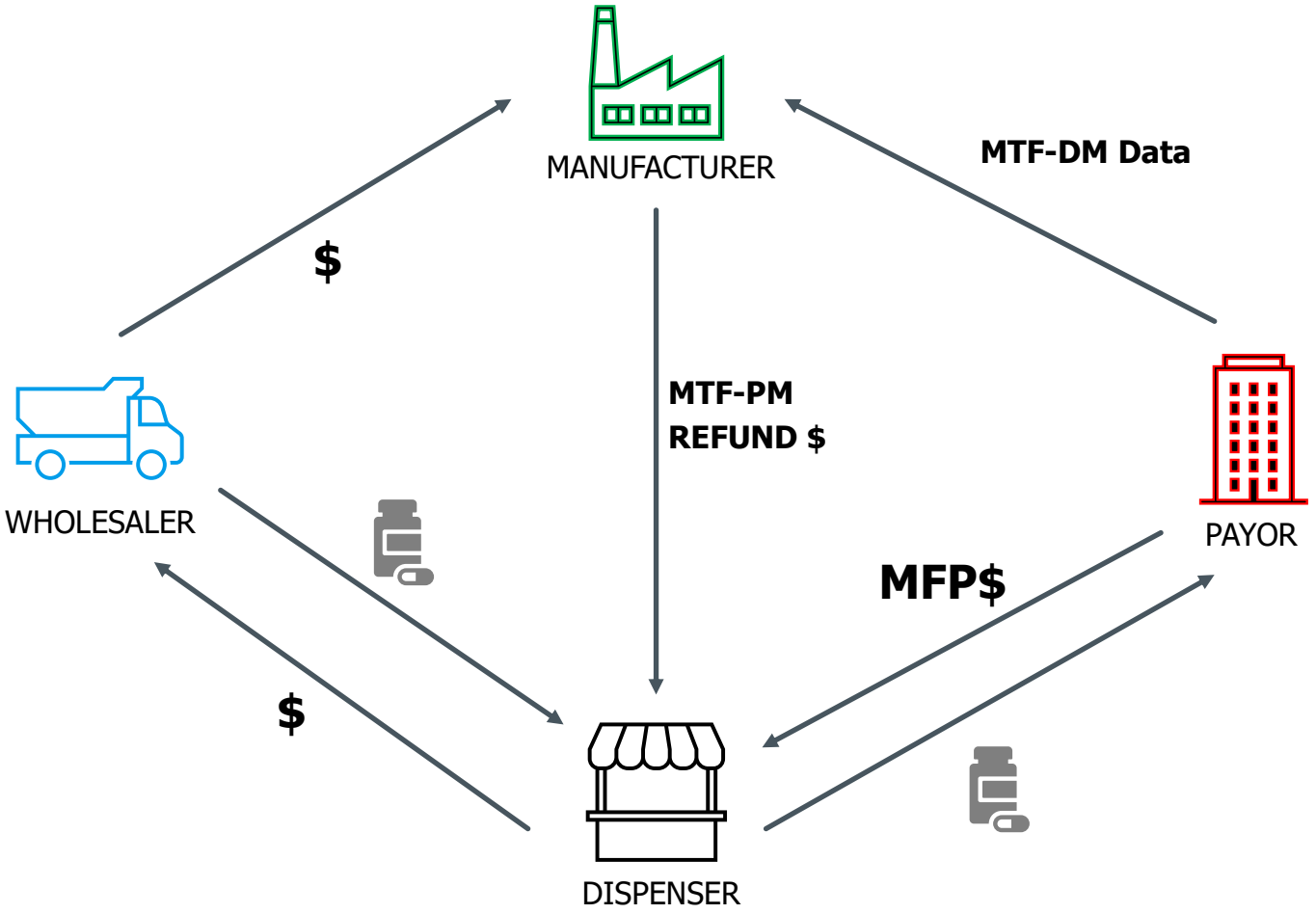
- **Refunds**: When a dispenser's drug acquisition cost exceeds the Maximum Fair Price, the dispenser will be refunded by the manufacturer within fourteen (14) days of receiving claim level data from the dispenser.

  - For example, if the dispenser's acquisition cost is $100, but the MFP is $80, the drug manufacturer will refund the dispenser $20.

The Medicare Drug Price Negotiation Program: Price Reimbursement

- **Data and Payment Processing**: Pharmacy MFP repayment will be addressed through two modules which comprise the Medicare Transaction Facilitator (MTF):
  - Data Module (MTF-DM): Enables the exchange of dispensing data between CMS, dispensers, and manufacturers.
  - Payment Module (MTF-PM): An optional service to assist manufacturers in distributing MFP refunds to dispensers.
- **Updated COPS**: In order to participate in Medicare, dispensers must enroll in the MTF-DM. Dispensers must also elect to receive repayments via EFT or paper check.

MFP Refund Process



The Medicare Drug Price Negotiation Program – What is Covered?

- CMS began its first round of negotiations in 2023. This round applied 10 drugs and negotiated pricing for Part D. Pricing went live as of Jan. 1, 2026.
- An additional set of 15 drugs (this will include some popular GLP-1 products) will have negotiated pricing go into effect in 2027 for Part D and 2028 for Part B.
- In the aggregate the total 40 drugs products that have been selected for negotiation thus far equate to approximately 36% of total Medicare spending on drugs.
- CMS estimates that the Medicare program would have saved $6B in spending if 2026 pricing were in effect in 2023 (when negotiation began).

Medicare Drug Pricing After the MDPNP

Medicare Part	Type of Drug	Payment Determination	Eligible for Negotiation by Government?
Part A	Drugs administered during inpatient stay	Usually included in DRG bundled payment to facility	No
Part B	Physician-administered drugs in outpatient setting	If paid separately, then ASP plus 6% Typically paid at MFP + 6%	Yes. Negotiation for 15 products to occur in 2027 with effective date of MFP coming Jan. 1, 2028
Part D	Outpatient retail drugs (ex., pharmacy dispensed)	Paid for by PDP Plan at rate negotiated between Plan and dispensing provider Payment capped at MFP for MDPNP drugs plus dispensing fee.	Yes. Currently 10 drugs impacted, with 15 more to take effect on Jan. 1, 2027

The experience so far

- The goals of the MDPNP are to move from a rebate-centric system to an up-front discount-based system and to ensure Part D plans have the same access price for MDPNP drugs.
- Payors are seeing consistent pricing and enjoying consistent reimbursement to dispensers.
- Medicare is reporting approximately 22% in savings as compared to 2023 data.
- Manufacturers are seeing reduced revenue and reporting reduced investment in small molecule development (i.e., pill-form drugs).

What in the MFP is happening to dispensers?

- Dispensers:
  - Facing substantial cash-flow issues (buy high, sell low).
  - Incurring administrative costs associated with reporting data; and
  - Seeing slow repayment at around 22-28 days for repayment to hit accounts despite 14 days provided by MDPNP.
  - Missing necessary reconciliation information to track refund payments.

How can hospitals adapt?

- Part B will not be affected until 2028. However, outpatient pharmacy may be seeing MFP-related hits.
- Prepare for revenue shifts, reduced Part B reimbursement, and supply chain changes.
- Conduct financial stress testing.
- Monitor MDPNP negotiated drug pipeline.
- Proactive communication among stakeholders.
- Review drug supply chain contracts (ex., payment terms with wholesalers).

340B Program Rebate Model

340B Rebate Model - History

- Beginning in Fall 2024, and in response to financial pressures caused by the Inflation Reduction Act and MDPNP, some larger drug manufacturers proposed converting their legally required "offer" to sell 340B drugs to 340B Covered Entities into a "rebate."

- In practice, 340B Covered Entities would be required to purchase MDPNP-subject drugs at their wholesale acquisition cost (WAC) and then request a rebate from the manufacturer reducing the purchase price to the 340B price.

    - If MFP is lower than 340B price, Manufacturer sends dispenser difference between MFP repayment and 340B Price, but no 340B rebate.

    - If 340B price is lower than MFP, then pharmacy receives 340B rebate but no MFP repayment.

- Goal is to move 340B (at least for MDPNP Drugs) to a back-end rebate system.

340B Rebate Model - History

- In fall 2024 and early 2025 HRSA received rebate model proposals from 4 drug manufacturers and 1 data processor.

- The proposed rebate programs generally required that:

  1. Covered Entities purchase all drugs at commercial prices (i.e., WAC-based)

  2. Dispensers then submit claims data through manufacturer vendor to request rebates.

  3. Manufacturer reviews claims data and then pays rebates to Covered Entities equal to the difference between the purchase price and the 340B ceiling price. *One manufacturer would instead offer credit on future purchases.

340B Rebate Model - History

- HRSA reviewed each proposal and advised manufacturers that HRSA's approval would be required before rebate models could be implemented.
- HRSA did not reject/approve 3 of the 4 manufacturer submissions but issued "violation letters" advising that if a rebate model were enacted without HRSA approval it would be considered non-compliant with 340B.
- HRSA also denied 1 manufacturer proposal.
- The drug manufacturers then sued arguing:
  - HRSA exceeded statutory authority by stating its pre-approval was required;
  - HRSA acted arbitrarily and capriciously in failing to approve proposals.

340B Rebate Model - History

- DC District Court held in HRSA's favor that:
  - HRSA has statutory authority to approve the use of any 340B rebate model "as provided by the Secretary"; and
  - HRSA did not act arbitrarily and capriciously with respect to 3 of the 4 manufacturer proposals as it had not denied/approved them and that HRSA must further consider 1 other manufacturer proposal.
- However, quicky after this lawsuit concluded, HRSA proposed guidance for the implementation of a 340B rebate model program.

340B Rebate Model - History

- The HRSA-proposed 340B Rebate Model would:
  - Begin on Jan. 1, 2026
  - Apply only to the 10 MDPNP drugs with MFPs
  - Require manufacturers to apply to HRSA for approval to implement a rebate program;
  - Apply to all purchases of 340B product regardless of payor (i.e., not limited to Medicare benefit drugs).
  - Require Covered Entities to purchase drugs at commercial prices, then submit claims data to manufacturers to receive rebates.
  - Manufacturers would bear the cost of administering the rebate program.

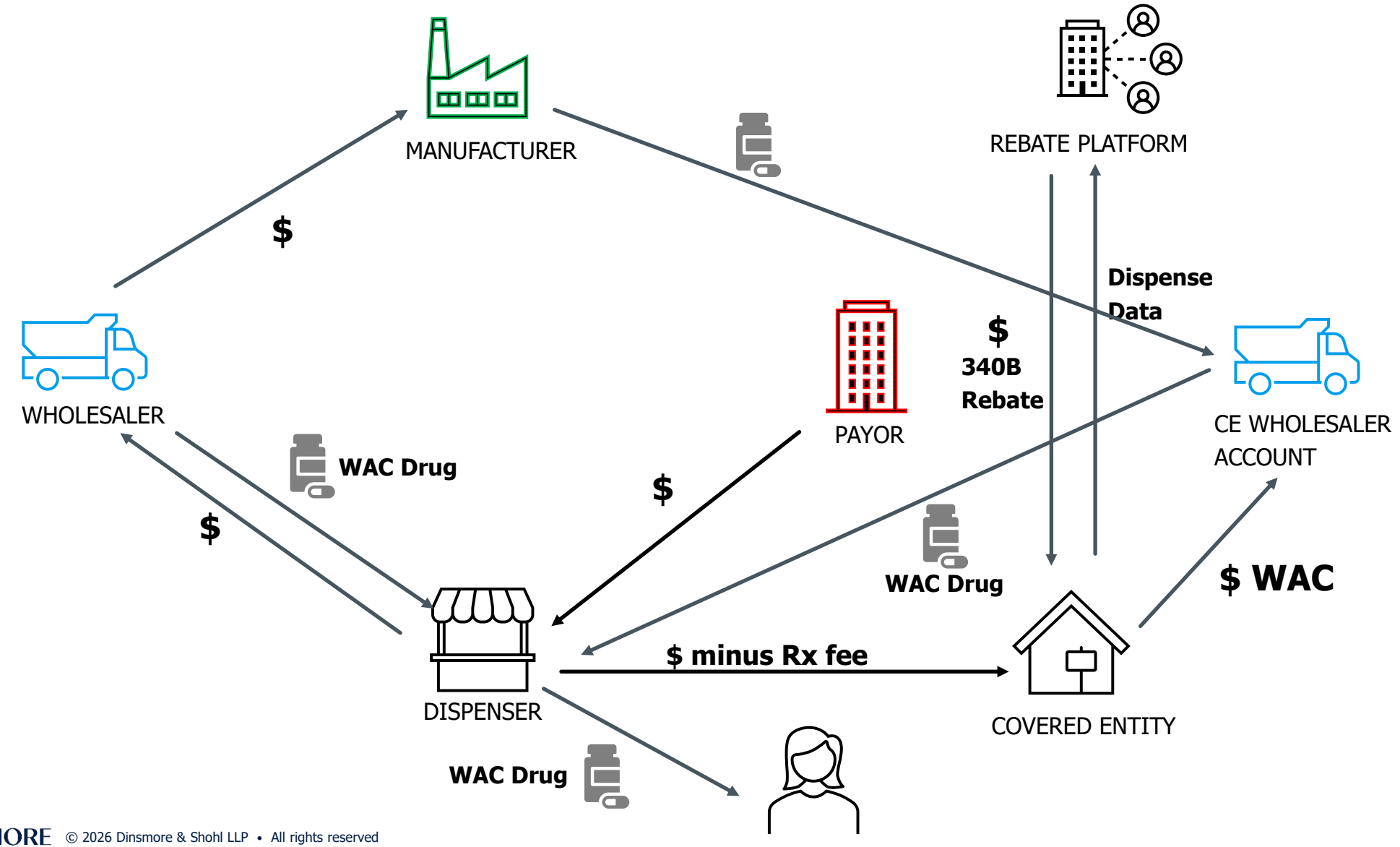
340B Rebate Model - History

- Under HRSA-proposed 340B Rebate Model manufactures must also:
  - Pay 340B rebates within 10 days of claims data submission
  - Not deny rebates based upon 340B non-compliance issues (ex., duplicate discounts or diversion)
  - Provide real-time reconciliation reports to Covered Entities
  - Specify whether rebates will be paid at the package or unit level
  - Allow Covered Entities to use their existing wholesalers for drug purchases
  - Ensure rebate platforms are secure, protect PHI, etc.

340B Rebate Model - History

- Under HRSA-proposed 340B Rebate Model Covered Entities must also:
  - Submit claims data within 45 days of dispensing (must including BIN/PCN)
  - Monitor submitted claims for approval/denial/payment
  - Work with state Medicaid agencies to determine what price to bill Medicaid for drug product.
    - This created the possibility for wildly varying reimbursement models under Medicaid and obligated states to quickly come up with means to ensure Medicaid is paying only the "actual acquisition cost" of drugs.

HRSA 340B Rebate Program Process – Contract Pharmacy

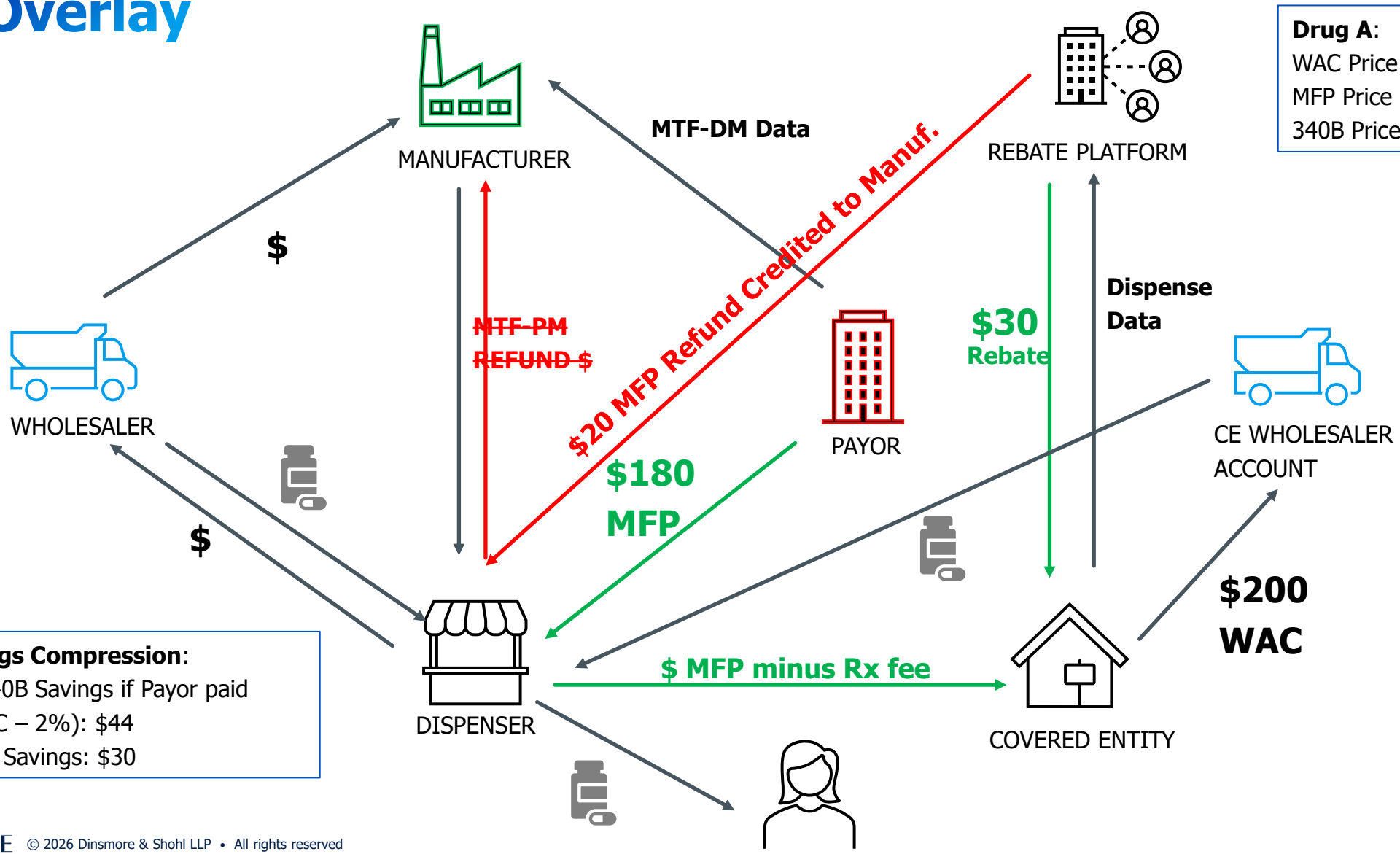


What About the MFP?

What About the MFP

BUCKLE UP

HRSA 340B Rebate Program Process – Contract Pharmacy with MFP Overlay



Drug A:
WAC Price = $200
MFP Price = $180
340B Price = $150

340B Savings Compression:

- Historic 340B Savings if Payor paid $194 (WAC – 2%): $44
- New 340B Savings: $30

Covered Entities File Suit

- Allege that HRSA violated Administrative Procedures Act (APA) by
  - Implementing 340B Rebate Program without supported administrative record
  - Failing to consider financial impacts/costs of 340B Rebate Program
  - Failing to consider 30+ years of industry reliance on current up front discount framework.
  - HRSAs record was comprised of a press release, a federal register notice, and FAQs.
  - Justification for program was provided only after litigation was filed.

Covered Entities File Suit

- US District Court of Maine issued a preliminary injunction in Covered Entities' favor noting:
  - HRSAs record was insufficient being comprised solely of a press release, a federal register notice, and FAQs.
  - Justification for program was provided only after litigation was filed.
  - Covered Entities were highly likely to succeed on their claim that the 340B Rebate Program violated the APA.

Covered Entities File Suit

- HRSA appealed District Court holding, but 1st Cir. Court of Appeals ultimately denied HRSA's request.
- HRSA rescinded the 340B Rebate Model Pilot Program on Feb. 10, 2026.
- However, HRSA will likely attempt to reintroduce the 340B Rebate Program.
  - HRSA issued a request for information on February 17, 2026 asking for stakeholder input on potential use of 340B rebates.
  - HRSA currently considering responsive comments and is expected to release a 340B Rebate Model Pilot Program potentially effective as of Jan. 1, 2027.
  - AHA estimates that a rebate program will inflict more than $1B in financial costs for 340B-eligible hospitals in the aggregate.

How can hospitals adapt?

- Monitor HRSA publications on the 340B Rebate Model
- Communicate with third party administrators and contract pharmacies about the program and means for data submission.
- Evaluate current cashflow and conduct financial stress testing. Consider what it would take for your organization to pay WAC pricing for all drugs.
- Consider revising vendor agreements to address rebate processing along with MFP refund processing.
- Monitor what drugs will become subject to the MDPNP going forward. Understand when and how such drugs could become incorporated into a 340B Rebate Model.
- Identify all internal stakeholders who need to provide input/make decisions with respect to drug procurement and supply chain management.

Executive Orders on Lowering Drug Prices

Executive Orders on Lowering Drug Prices

- Executive Order 14273 – Issued on April 15, 2025
- Key Provisions:
  - Medicare "better value" programming that would apply to drugs other than those in the MDPNP.
  - Improving Transparency of MDPNP and Improve Investment in Small Molecule (i.e., pill form) drugs.
  - 340B Cost of Dispensing Survey (2018 all over again)
  - PBM Transparency
- Note: Most Favored Nation Pricing is not directly addressed but mentioned as a higher-level policy goal.

Executive Orders on Lowering Drug Prices

- Presidential Proclamation 11020 – Issued on April 9, 2026 – "Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients into the United States"
- Key Provisions:
  - Asserts that imported drugs and APIs present a threat to national security.
  - Directs federal agencies to use trade authorities (ex., tariffs) to incentivize shifting production into the United States and to align pricing with Most-Favored-Nation benchmarks.
  - Creates tariff framework for imported drugs (currently excluding generics):
    - 0% for companies that enter into MFN Pricing agreements and into tariff agreements that commit to US onshoring
    - 15% tariffs for products originating from "allied jurisdictions": Japan, South Korea, Switzerland, Liechtenstein. UK subject to 10% but possibly 0% if UK enters into pricing agreement with US.
    - 20% tariffs for companies with tariff agreements that include approved domestic manufacturing plans.
    - 100% tariffs for all patented pharmaceutical products and ingredients.

Executive Orders on Lowering Drug Prices – What are we doing?

- Drug pricing policy developers at federal level are focusing on what other countries pay.
  - GLOBE and GUARD models – Rebates where pricing exceeds international benchmark
  - Adjusting Imports Proclamation – Penalizing importation/encouraging domestic manufacturing
- Hospitals will likely be asked to produce more acquisition cost data, specifically identifying the price at which product is actually acquired.
- Unclear whether Medicare payment will be adjusted to address discounted drug acquisition (ex., 340B drugs, GPO acquisition, etc.) but movement that way is likely.
  - Note: Medicare Part B is reissuing a 340B cost of acquisition survey. CMS used previous survey to lower Part B reimbursement by 28.5%.

Executive Orders on Lowering Drug Prices

- More reimbursement pressure will come. Run financial stress testing.
- Identify what drugs are your largest sources of cost and review purchasing relationships for those products.
- Identify trends in WAC price decreases and ensure your pricing is updated accordingly. CMS-published negotiated price files are your friend.
- Routinely review purchasing agreements and monitor pricing for errors, minor inflation, etc.
- Encourage system-wide wholesaler/distributor contracting. Pricing can vary among contracted relationships and volume.
- Understand volume and its effects on pricing, including purchase commitments, supply commitments, etc.
- **IT IS NOT ALL DOOM AND GLOOM, BUT A TIME TO REFOCUS ON PROCUREMENT/REIMBURSEMENT**

Questions?

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