

IRA Impacts on the 340B Program

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STATEMENT

Felicity Homsted has no relevant financial relationships with ineligible companies to disclose.



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Mark Ogunsusi has the following relevant financial relationships or commercial interests in relation to this presentation: minor stock in Pfizer, Merck, and GlaxoSmithKline

The materials and discussions contained in this presentation may not be relied upon as legal advice.

All of the relevant financial relationships listed for this individual has been mitigated.



LEARNING OBJECTIVES

At the completion of this activity, the participant will be able to:

- Describe key provisions of the IRA that impact Ohio 340B covered entities and their contract pharmacies;
- Identify critical challenges involved with proposed implementation of the IRA that may impact 340B program participation and contract pharmacy arrangements
- Analyze potential outcomes and advocacy perspectives for operationalization of IRA components that impact 340B savings, covered entity-drugmaker relations, and eligible patient identification.



Inflation Reduction Act Updates

Medicare CY 2025 Physician Fee Schedule
(Proposed Rule)



Inflation Reduction Act (IRA)

Two Major Components Impacting 340B

- Medicare Inflationary Drug Penalties for Medicare Part B and D
 - Established new requirements under which drug manufacturers **must pay inflation rebates** if they **raise their prices** for certain Part B and Part D drugs **faster than the rate of inflation**.
 - “Rebatable drug,” as a single source drug or biological product (including a biosimilars)
 - Excludes rebatable drugs for which the average total allowed charges is below \$100* for all four calendar quarters.
- Negotiation of Maximum Fair Price (MFP)
 - Pricing on initial 10 drugs takes effect January 1st, 2026

* Increased by the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.



IRA Rebate Timelines

Part B & Part D Rebate Reporting & Invoicing Timelines

Program	Rebate Period	Reporting Deadline	Invoicing Deadline
Medicare Part B	Calendar Quarter	6 months post-quarter	Sept 30, 2025 (for 2023-2024)
Medicare Part D	12-month Period	9 months post-period	Dec 31, 2025 (for 2022-2024)



2025 Proposed Rules Medicare Part B

Section 1847A(i)(3)(B)(ii)(I) of the Act specifically excludes billing units of drugs for which the manufacturer provides a discount under the 340B Program from the billing units of drugs for which a manufacturer may otherwise have a Part B inflation rebate liability.

- CMS proposes in § 427.303(b)(1)(ii) excluding separately payable billing units in claim lines for institutional providers with the **“JG” and “TB” modifiers** from identified final action **claims with dates of service through December 31, 2024.**
- CMS proposes to codify policies established in section 50.8.1 of the revised Medicare Part B Drug Inflation Rebate Guidance in § 427.303(b)(1)(iii) by excluding separately payable billing units in claim lines with the **“TB” modifier** from identified final action claims with **dates of service on or after January 1, 2025.**

TB

CMS New Stance: Prospective 340B Claims Identifiers



Initial guidance suggested including a 340B Claims Modifier at dispense time.



Covered entities, pharmacies, & others opposed the 340B Claims Modifier as the method for identifying 340B.



CMS' Current Stance -Will not pursue Modifiers, may be revisited in future rulemaking.

Estimation Methodology to Remove 340B Units

Sample Part D Rebate 340B Exclusion

Total Part D Units Dispensed	1,000
Estimation Percentage (340B Purchases/Total Sales)	10%
340B Units Excluded	100
Net Part D Rebatable Units	900

- **Statutory Requirement Compliance**
 - Removal of 340B units from rebate calculations starting January 1, 2026.
- **Proposed Policy for Unit Removal**
 - Based on a calculated percentage reflecting 340B purchases relative to total sales.
- **Estimation 340B Percentage**
 - Total 340B units purchased by covered entities divided by total units sold.
 - Proposes **using 340B PVP data to estimate total 340B units** purchased by CEs.

2026-2027



Part D Estimated Rebate Calculation

Total number of units dispensed under Part D determined under § 428.203(a) (total in 12-month period), minus the units determined under § 428.203(b)(1) (no longer met rebate calculation): 1,000

Estimation percentage:

- Total number of units purchased by CE in 340B Program: 5,000
- Total units sold: 50,000
- 5,000 divided by 50,000 = 10%
- 340B units excluded under § 428.204(b)(2): $10\% \times 1,000 = 100$ units

Medicare seeks rebates on 1000 (total units) - 100 (340B units) = **900 Units**

Medicare Part D - 340B Claims Repository

CMS is soliciting comments on establishing a Medicare Part D claims data repository to comply with the requirement to exclude 340B from total Part D rebatable units.

Key Aspects of the Proposed Medicare Part D Claims Data Repository

Data Submission	Covered entities to submit 340B-identified Part D claims data
Repository Function	Stores data elements, no further 340B status verification
Data Accuracy	Attestation required, methods for accuracy review sought
Rebate Calculation Impact	Data matched to PDE records; matched units excluded

<https://public-inspection.federalregister.gov/2024-14828.pdf>

2028 and Beyond!

Medicare Part D - 340B Claims Repository

CMS is considering requiring covered entities to submit the following data elements from Part D claims for covered Part D drugs that are purchased under the 340B Program and dispensed to Medicare Part D beneficiaries:

- (1) Date of Service (that is, the date the prescription was filled by the pharmacy);
- (2) Prescription or Service Reference Number;
- (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); and
- (4) Dispensing Pharmacy NPI.

CMS will provide Rebate Reconciliation Reports to manufacturers 11 and 35 months after initial report.

CMS is soliciting comments on the process and timing for covered entities to submit this revised data to the repository after the end of the applicable period.

2028 and Beyond!

COMMENT SOLICITATION ON REQUIRING COVERED ENTITIES TO SUBMIT 340B CLAIMS DATA TO THE REPOSITORY

CMS Comment Solicitation

- Seeking input on requiring 340B claims data submission to a repository
- Utilizing authority under sections 1860D-14B(b)(1)(B), 1102(a), and 1871(a)(1) of the Act

Role of 340B TPAs

- Contracted by covered entities to determine 340B eligibility
- Potential requirement for TPAs to submit data on behalf of covered entities

Proposed Data Elements

- Date of Service, Prescription Number, Fill Number, Dispensing Pharmacy NPI
- Essential for excluding 340B units from Part D drug inflation rebate calculations

Benefits of Direct Submission

- Allows CMS to directly receive data from participating entities
- Eliminates need for intermediary processes

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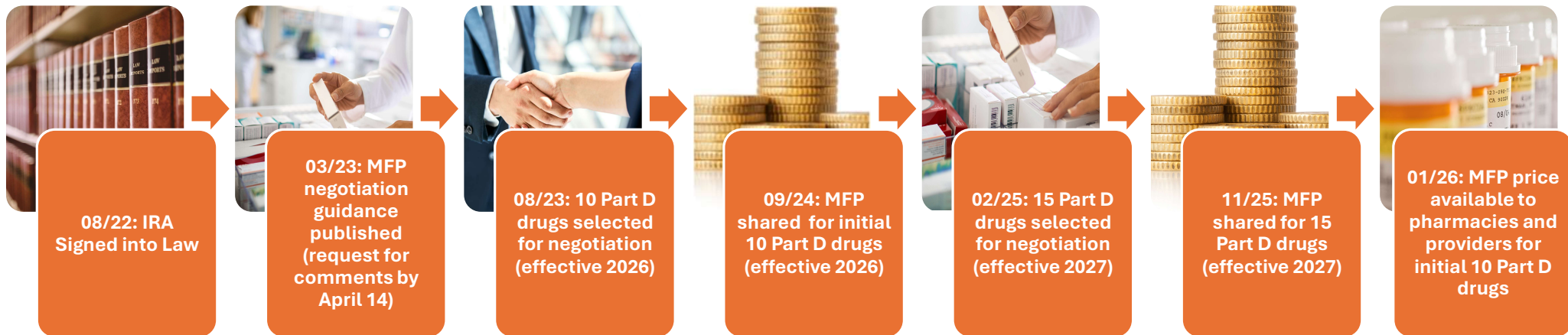
Maximum Fair Prices & The Medicare Transaction Facilitator

Maximum Fair Price Negotiations

- Sections 11001 and 11002 of the IRA, the Secretary is required to establish the Negotiation Program to negotiate Maximum Fair Prices (MFP) for certain high expenditure, single source drugs covered by Medicare.
- Drugs ranked by expenditures under both Medicare Parts B and D
 - Selection factors include time in market, price, Consumer Price Index (CPI) growth (inflation)

Year Effective	Drugs Negotiated	Total
2026	10 Part D drugs	10
2027	15 Part D drugs	25
2028	15 Part B & Part D drugs	40
2029 & every year after	20 Part B & Part D drugs	60

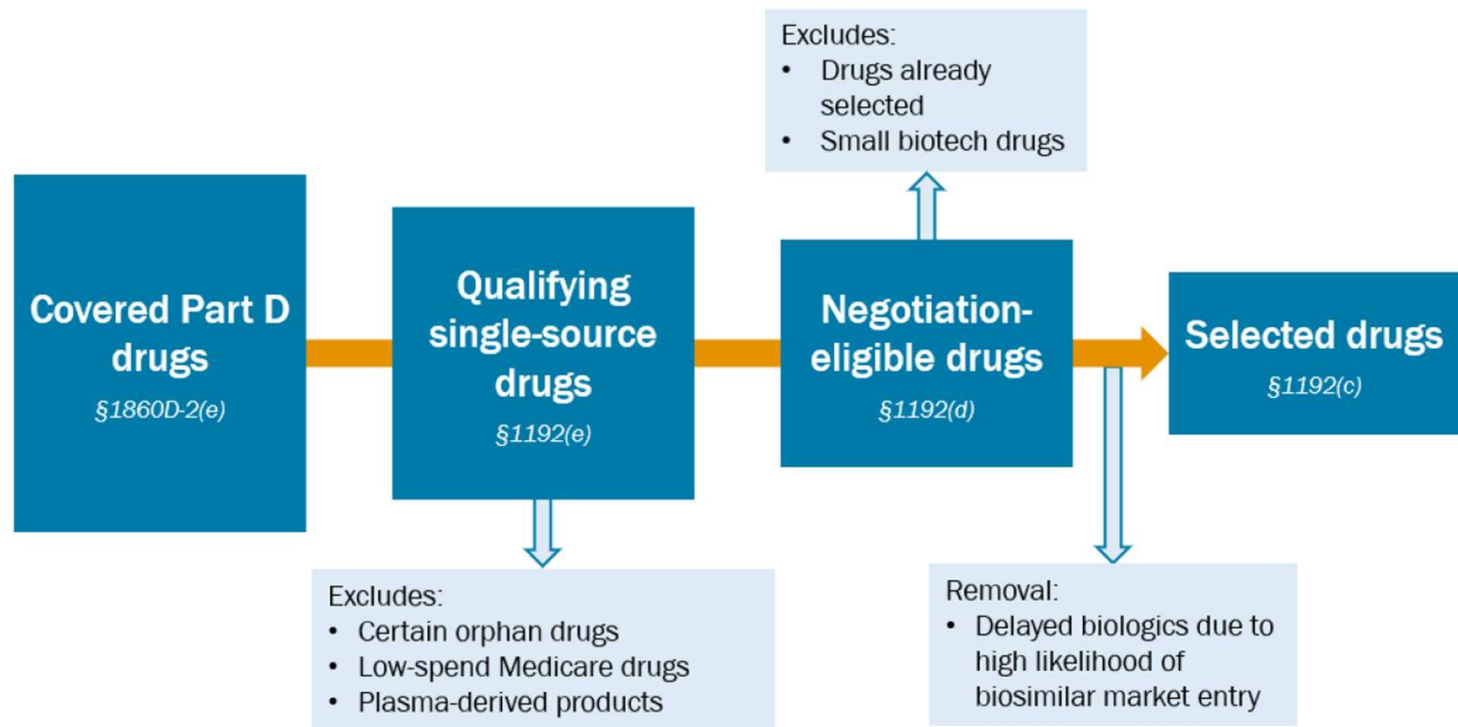
IRA Timeline



<https://www.cms.gov/files/document/10522-inflation-reduction-act-timeline.pdf>



MFP Negotiation Selection Process

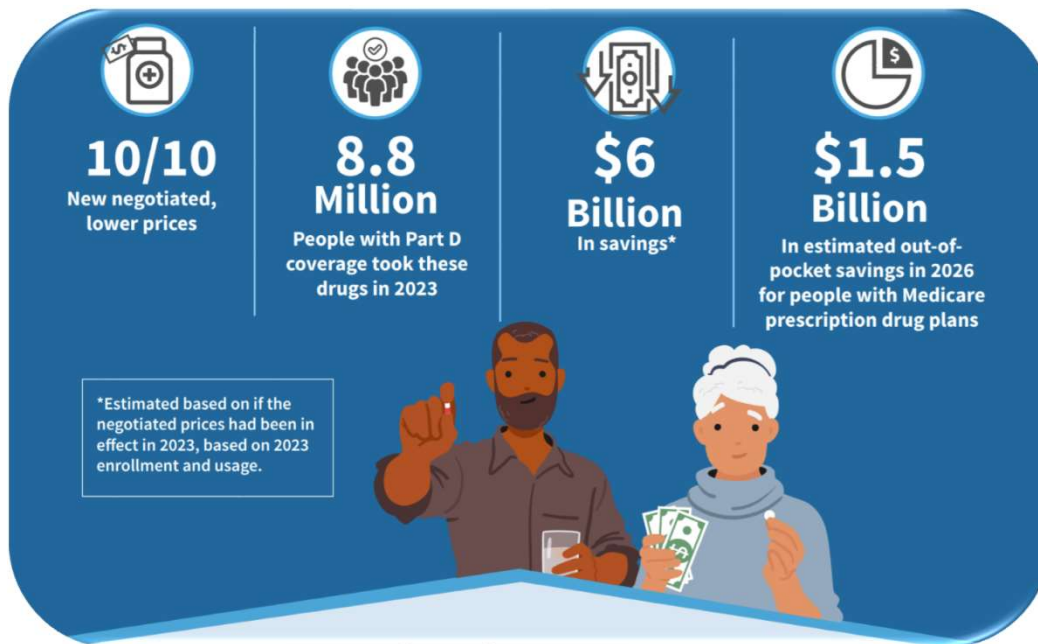


Initial 10 Drugs Negotiated by Medicare

Brand	Manufacturer	Indication
Eliquis	Bristol-Myers Squibb	Anticoagulant
Enbrel	Amgen	Immunomodulator (Rheumatology)
Entresto	Novartis	Heart Failure
Farxiga	AstraZeneca	Diabetes
Imbruvica	AbbVie	Immunomodulator (Oncology)
Januvia	Merck	Diabetes
Jardiance	Boehringer Ingelheim	Diabetes
Novolog/FIASP	Novo Nordisk	Diabetes
Stelara	Johnson & Johnson	Immunomodulator (Rheumatology)
Xarelto	Johnson & Johnson	Anticoagulant

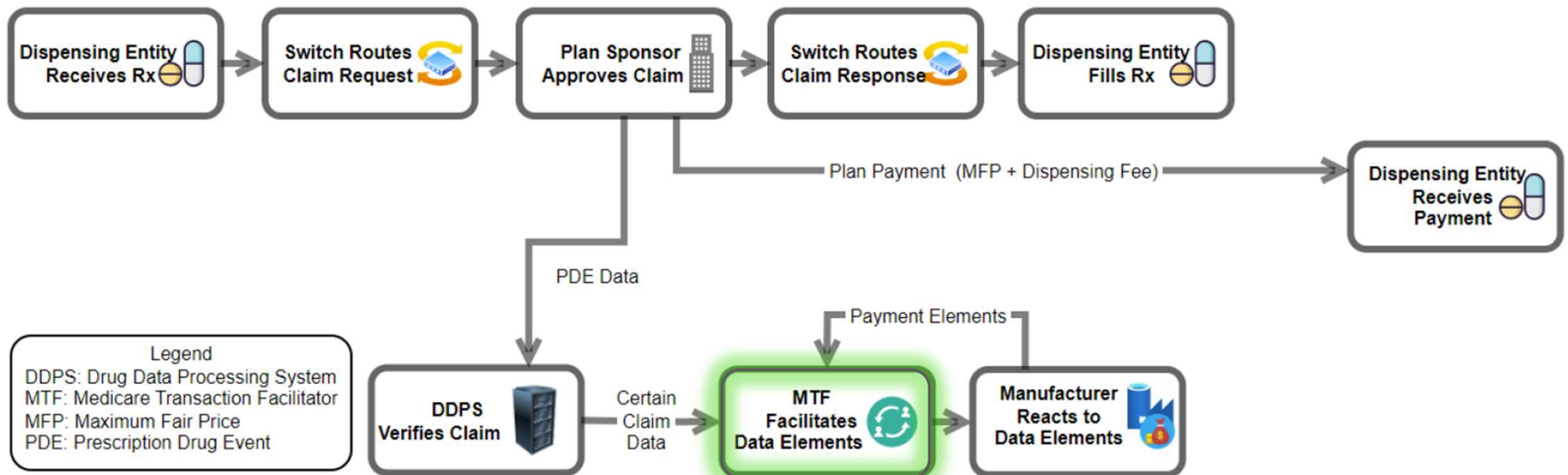
Initial negotiated Maximum Fair Prices (MFP) take effect on **January 1st, 2026**

Medicare Messaging on MFP



<https://www.cms.gov/files/document/infographic-negotiated-prices-maximum-fair-prices.pdf>

Medicare Transaction Facilitator (MTF) Data Flow



<https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>

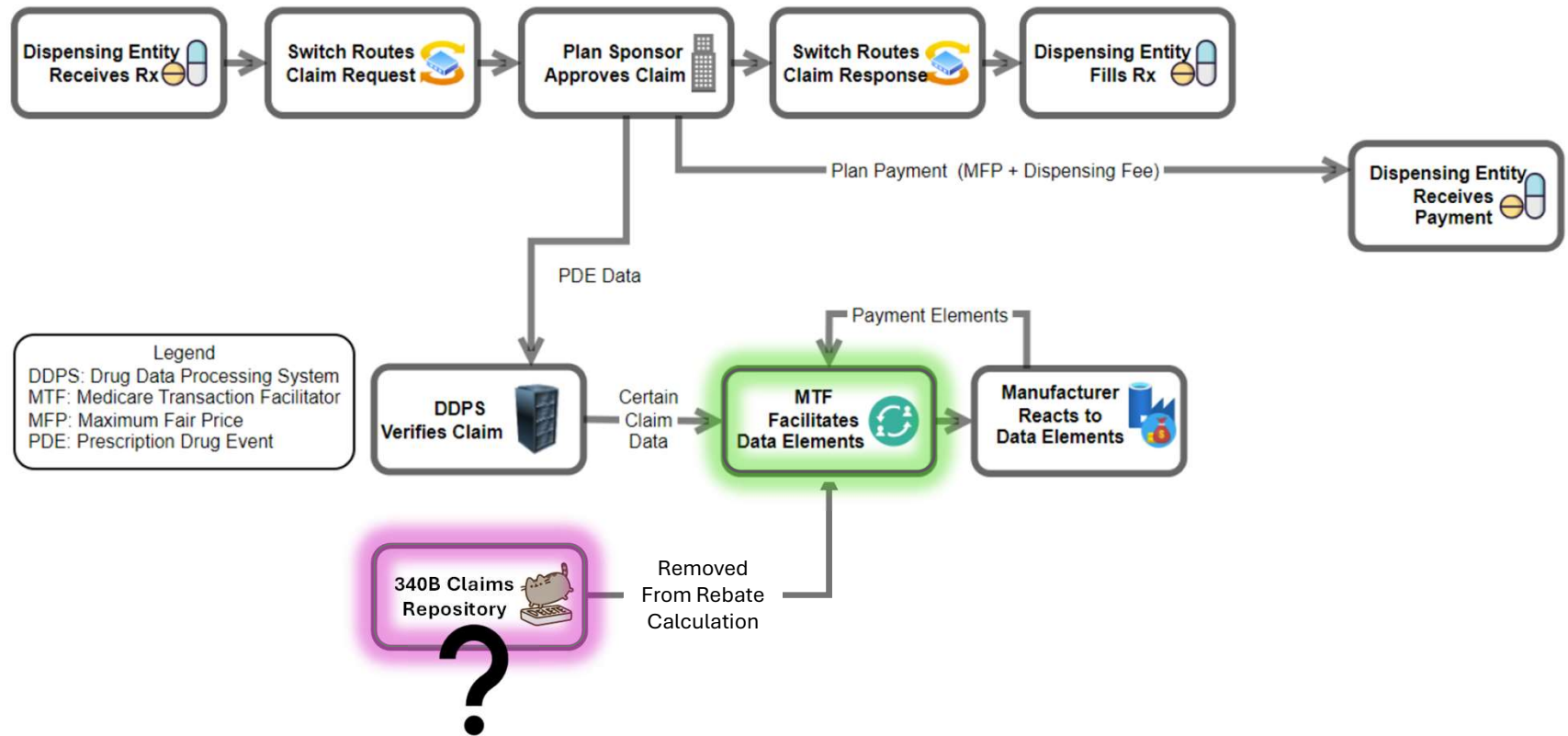
MFP & 340B Pricing

- CEs will be reimbursed at the MFP when billing Medicare for negotiated drugs
- May purchase lower of MFP or 340B for use in Medicare patients
 - Generally, 340B price at or below MFP
 - Duplication of discounts need to be prevented for 340B, Medicaid, and Medicare

If MFP sets a new Best Price there maybe up to a 2 quarters until seen in 340B price, due to calculation lag time.



MTF + 340B Data Repository Data Flow



<https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>

Potential MFP Drugs for 2027

- Ozempic - Novo Nordisk (Diabetes)
- Ibrance - Pfizer (Oncology)
- Xtandi - Pfizer (Oncology)
- Trelegy Ellipta - GSK (Asthma COPD)
- Austedo - Teva (Huntington's Disease)
- Linzess - AbbVie (IBS)
- Pomalyst - BMS (Oncology)
- Vraylar - AbbVie (Schizophrenia/Bipolar)
- Venclexta - AbbVie (Oncology)

Ozempic on Wall Street's list for 2027 Medicare drug negotiations

By Michael Erman

August 23, 2024 12:34 PM EDT · Updated 4 days ago



Projections: Initial & Potential Negotiated by Medicare

Count	Manufacturer	Drugs
2	Bristol-Myers Squibb	Eliquis, Pomalyst
1	Amgen	Enbrel
1	Novartis	Entresto
1	AstraZeneca	Farxiga
3	AbbVie	Imbruvica, Vraylar, Linzess
1	Merck	Januvia
1	Boehringer Ingelheim	Jardiance
2	Novo Nordisk	Novolog/FIASP, Ozempic
2	Johnson & Johnson	Stelara, Xarelto
2	Pfizer	Ibrance, Xtandi
1	GSK	Trelegy Ellipta
1	Teva	Austedo

Theoretical

Negotiated MFPs 10 Drugs in 2026, 15 drugs in 2027

References

- Medicare Drug Price Negotiation Program: Draft Guidance-
<https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>
- <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-next-steps-implementation-2026.pdf>
- <https://www.congress.gov/bill/117th-congress/house-bill/5376>
- <https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation>
- <https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf>



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