

Inflation Reduction Act: 2026 Pharmacy Implications

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Agenda

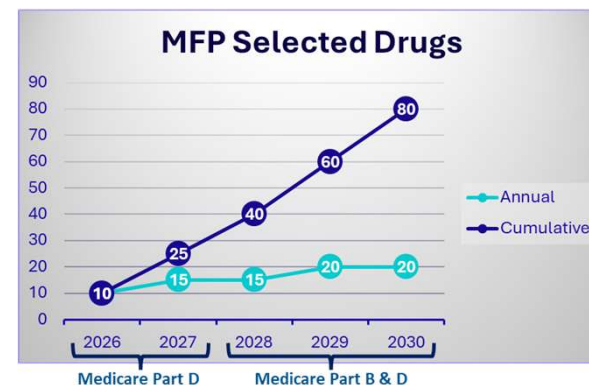
1. Medicare Maximum Fair Price & Medicare Transaction Facilitator
2. 340B Rebate Pilot
3. Most-Favored Nations (MFN)
4. Medicare Inflationary Penalties

Inflation Reduction Act: Maximum Fair Prices

The Inflation Reduction Act: Medicare Impact

- Inflation Reduction Act was signed into law Aug 16th, 2022.
 - Included provisions to address rising drug prices:

Provision	Effective	Applies To
Inflationary Rebate Penalties	2023	Part B & D drugs
\$35 Insulin Co-Pay Cap	2023	Medicare
Vaccine Cost-Sharing Elimination	2023	Medicare Part D
\$2,000 Out-of-Pocket Cap	2025	Medicare Part D
Medicare Drug Price Negotiation	2026*	Part B & D



- To be included in Medicare Drug Price Negotiation, must be:
 - A **single-source** brand-name drug or biological product (with no bona fide generic or biosimilar)
 - On the market for at least 9 years for small-molecule drugs & 13 years for biologics
 - High Medicare spend in previous 12 months
- Negotiation starts with **Part D** in 2026 & adding **Part B** in 2028.
 - Drugs selected for 2028 are due to be announced February 1st, 2026.



2026 First 10 Drugs Negotiated by Medicare

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

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

- Medicare Part D prescriptions will be reimbursed at MFP + dispensing fee
- 83% of NDCs will have lower 340B prices than MFP
- ~77% of 340B savings has been eroded by negotiated MFPs



15 14 MFP Drugs for 2027

Brand	Manufacturer	Indication
Austedo	Teva	Huntington Dz
Breo Ellipta	GSK (& Prasco)	Asthma & COPD
Calquence	AstraZeneca	Oncology
Ibrance	Pfizer	Oncology
Janumet; Janumet Xr	Merck	Diabetes
Linzess	Allergan	GI Indications
Ofev	Boehringer Ingelheim	Pulmonary Fibrosis
Otezla	Amgen Inc	Rheumatology
Ozempic; Rybelsus; Wegovy	Novo Nordisk	Diabetes & Weight Loss
Pomalyst	<i>Bristol-Myers Squibb</i>	Oncology
Tradjenta	Boehringer Ingelheim/ <i>Lilly</i>	Diabetes
Trelegy Ellipta	GlaxoSmithKline	Asthma & COPD
Vraylar	Allergan	Antipsychotic
Xifaxan	Bausch	GI Indications
Xtandi	Astellas	Oncology

2027 negotiated Maximum Fair Prices will be announced **November 30th, 2025**

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



Exiting the Negotiated List: Option 1

- Before or During Negotiation, if CMS identifies a “bona fide” generic or biosimilar drug is being marketed before or during the negotiation process:
 - The negotiation will not begin or be suspended, & no maximum fair price (MFP) will be negotiated.
- Removal from 2027 Selected Drug List:
 - To be removed from the 2027 list, CMS must make the determination between Feb 1, 2025, & Nov 1, 2025.
- If a generic or biosimilar enters the market after the MFP is set: The drug will be removed from future selected drug lists, depending on when CMS makes the determination.
 - Determination between Nov 2, 2025 – **Mar 31, 2027**: MFP applies only in 2027. Drug is removed for **2028**.
 - Determination between Apr 1, 2027 – **Mar 31, 2028**: MFP applies in 2027 & 2028. Drug is removed for **2029**.

<https://www.kff.org/medicare/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/?entry=table-of-contents-what-happens-if-a-generic-or-biosimilar-drug-becomes-available-after-a-drug-has-been-selected-for-negotiation#initial-offer>



Medicaid Changes

Bausch Health and Salix will cease its participation in two optional federal drug pricing programs (the Medicaid drug rebate program and the 340b pricing program) effective October 1, 2025.

The company remains committed to Medicaid patients who have been prescribed our products and to maintaining continuity of treatment. Medicaid patients whose plans no longer provide coverage for our products may be eligible for Xifaxan through our Patient Assistance Program (PAP).

The details on how to enroll can be found at www.bauschhealthpap.com or by calling **1-833-862-8727**.

[LEARN ABOUT MEDICAID CHANGES](#)

Exiting the Negotiated List - Option 2: The manufacturer terminates their Pharmaceutical Pricing Agreement (e.g., Bausch)



Upcoming IRA Timeline

OPA's 60-day deadline to publish MFR 340B rebate pilot plans for 1/1/2026 start

Nov 2, 2025

CMS publishes negotiated Maximum Fair Prices (MFP) for 2027 Selected Drugs

Nov 30, 2025

2026 MFPs prices launch (+/- 340B Rebate Pilot)

Jan 1, 2026

CMS publishes 2028 list of 15 drugs selected for negotiation & any drugs selected for renegotiation

Feb 1, 2026

CMS publishes initially negotiated MFPs for 2028 Drugs & any renegotiated MFPs

Nov 30, 2026

MTF Enrollment (Entity-Owned Pharmacies Only)

MTF Enrollment Requirements

- CMS finalized a requirement that Part D plan sponsors, starting in contract year 2026, include in their pharmacy agreements provisions requiring the pharmacies to be enrolled in the MTF.
 - Pharmacies must sign up for the MTF based on their contractual agreements with Medicare, regardless of if they are filling MFP prescriptions or not.

6. Medicare Transaction Facilitator Requirements for Network Pharmacy Agreements

We are finalizing as proposed our proposal to amend § 423.505 by adding paragraph (q), requiring that Part D sponsors' network participation agreements with contracting pharmacies, including any contracts with any first tier, downstream, and related entities require such pharmacies to be enrolled in the Medicare Drug Price Negotiation Program's ("Negotiation Program") Medicare Transaction Facilitator Data Module ("MTF DM") and that such pharmacies certify the accuracy and completeness of their enrollment information in the MTF DM. We believe the inclusion of the requirement for Part D sponsors' network pharmacies to be enrolled in the MTF DM that will be added to Part D sponsors' network contracts with pharmacies will facilitate continued beneficiary access to selected drugs that are covered Part D drugs, promote access to negotiated MFPs under the Negotiation Program for both beneficiaries and dispensing entities, and help ensure accurate Part D claims information and payment.



MTF Data Module Enrollment Phase

CMS began enrolling pharmacies & other dispensing entities in the MTF DM beginning in June 2025.

The MTF interfaces with NCPDP to help facilitate enrollment.

The MTF DM will allow dispensing entities to:

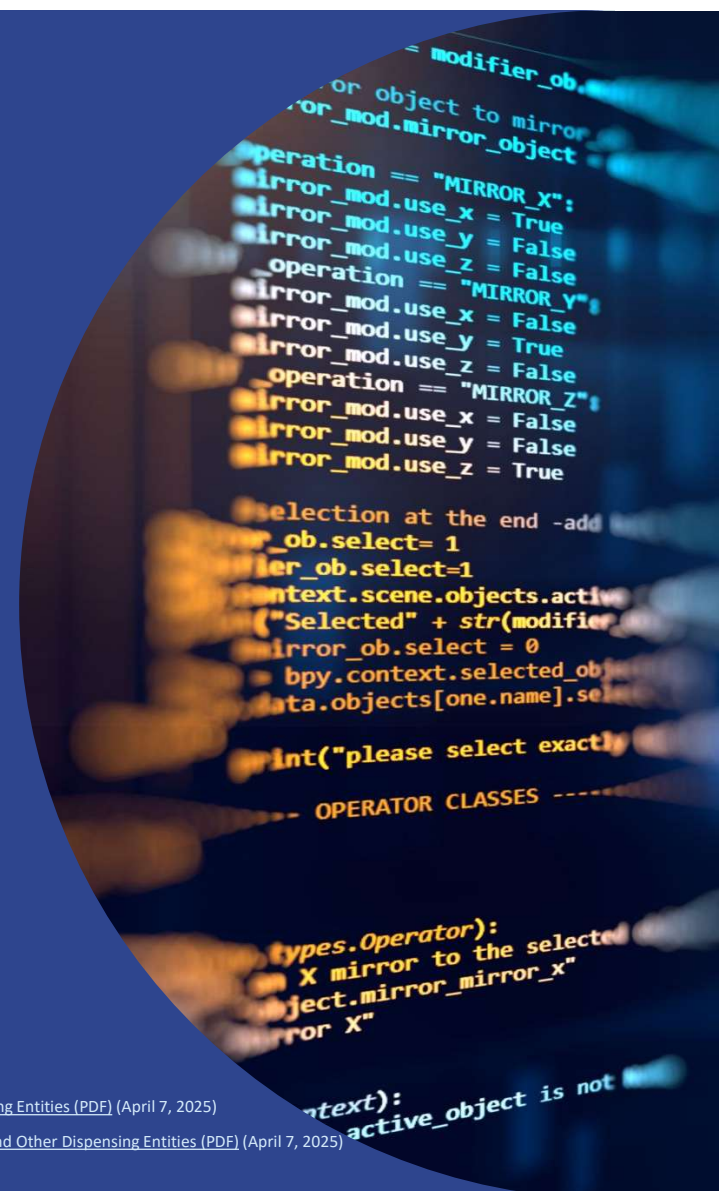
- **Self-identify** as anticipating material **cash flow issues**
- Conduct Enrollment within MFP DM
- **Review manufacturer MFP Effectuation Plans**, including plans for dispensing entities self-identifying with cash flow issues

You-Tube videos available

- <https://www.youtube.com/watch?v=xrGOvqfLcQ>
- <https://www.youtube.com/watch?v=AUebtiiuD1M>

[Medicare Transaction Facilitator: Fact Sheet for Pharmacies and Other Dispensing Entities \(PDF\) \(April 7, 2025\)](#)

[Medicare Transaction Facilitator: Frequently Asked Questions for Pharmacies and Other Dispensing Entities \(PDF\) \(April 7, 2025\)](#)



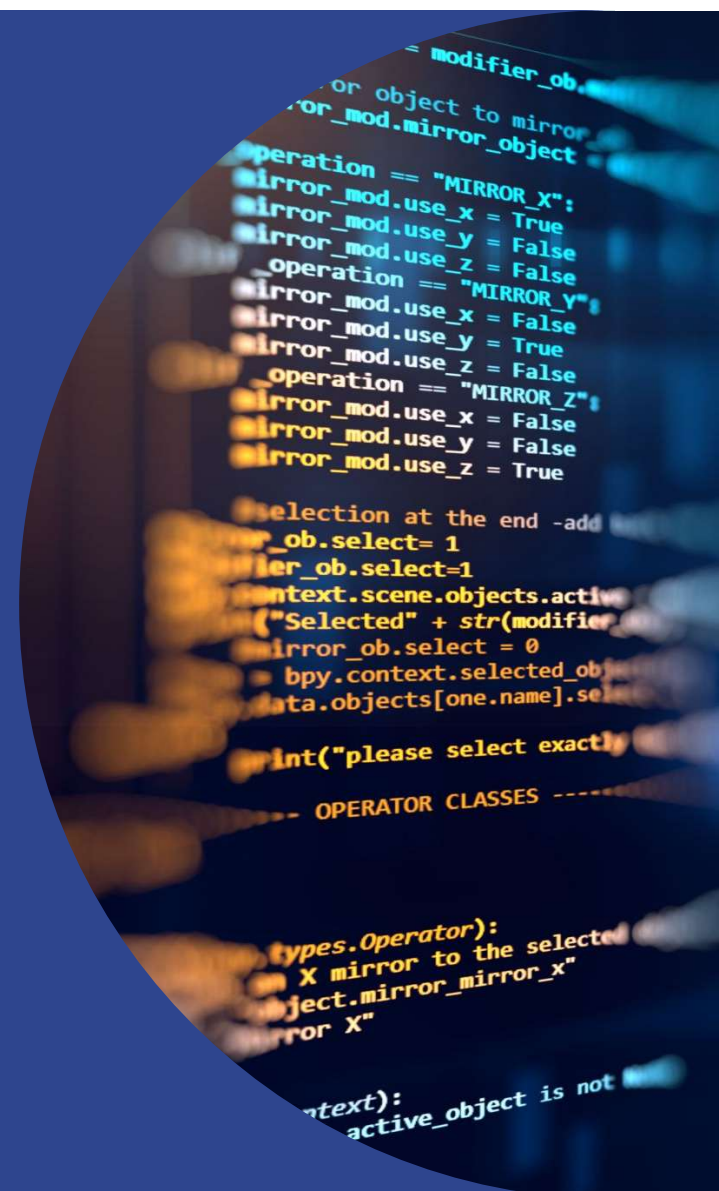
MTF Data Module Implementation Phase

The MTF DM will allow dispensing entities to:

- **Receive MFP refund payments** from Manufacturers who have opted in to the MTF Payment Module
- **Receive remittance for payment** made by paper check or Electronic Remittance Advice that uses the X12 835 standard
- **Submit complaints or disputes**
- **View reports on the status of PDE data processing** through the MTF DM user interface, to aid in financial planning

[Medicare Transaction Facilitator: Fact Sheet for Pharmacies and Other Dispensing Entities \(PDE\) \(April 7, 2025\)](#)

[Medicare Transaction Facilitator: Frequently Asked Questions for Pharmacies and Other Dispensing Entities \(PDE\) \(April 7, 2025\)](#)



Getting Ready to Enroll in The MTF

Primary Information .0123456 - Sample Pharmacy Status **Active** [Edit Profile](#)

Addresses

NPI Information

License Information

Class & Taxonomies

Services

Contact Information

Active Relationships

FWA

Actions ▾

- [Edit Profile](#)
- [Add Notes](#)
- [Missing Credential Documents](#)
- [Missing Mandatory Fields](#)
- [Credential My Profile](#)

Pharmacy Email

Pharmacy Email
Sample.Pharmacy@Pharmacy.com

[Print](#)

Authorized Official

Prefix Mrs.	Title Chief Executive Officer
First Name Janice	Email Jane.Doe@Pharmacy.com
Middle Initial	Phone 867-867-5309
Last Name Doe	Extension
Suffix	Fax
Degree	

Authorized Signatory Official (AO) in the MTF
MUST have authority to legally bind the
organization in agreements



Why Validate Name Listed in NCPDP?

The screenshot shows the Medicare Transaction Facilitator (MTF) interface. The main heading is "Verify your information". Below it, there is a "Welcome," message and a list of steps. Step 1 is "Select an email address", which is highlighted. The text for step 1 reads: "Your name, William Collin, is listed in the NCPDP Pharmacy Database as a point of contact for several email addresses. Each address is associated with one or more organization that you can choose to add to your MTF profile. To get started, choose select organizations for an address that belongs to you or an address that belongs to you." Step 2 is "Add organizations to your profile", with text: "You can add one or more organizations to your MTF profile. You will be able to add more organizations later." A modal message is overlaid on the screen, titled "Your name is not listed as a point of contact". The modal text says: "Your name, [redacted] does not appear as a point of contact for any organizations in the NCPDP Database. Before you can create your MTF profile, you'll need to add your name and a corresponding email address to the NCPDP database. Note: It may take at least two weeks for the MTF to receive new NCPDP data after you update your information. Once that information is available, you can create your profile. Another option is to have a different point of contact from your organization invite you to the MTF." A "Sign out" button is visible in the bottom right corner of the modal.

Medicare Transaction Facilitator (MTF)

Verify your information

Welcome,

- 1 Select an email address**

Your name, William Collin, is listed in the NCPDP Pharmacy Database as a point of contact for several email addresses. Each address is associated with one or more organization that you can choose to add to your MTF profile. To get started, choose select organizations for an address that belongs to you or an address that belongs to you.
- 2 Add organizations to your profile**

You can add one or more organizations to your MTF profile. You will be able to add more organizations later.

Your name is not listed as a point of contact

Your name, [redacted] does not appear as a point of contact for any organizations in the NCPDP Database.

Before you can create your MTF profile, you'll need to add your name and a corresponding email address to the NCPDP database.

Note: It may take at least two weeks for the MTF to receive new NCPDP data after you update your information. Once that information is available, you can create your profile.

Another option is to have a different point of contact from your organization invite you to the MTF.

[Sign out](#)

If not an exact match, it takes up to 2 weeks for NCPDP corrections to reach the MTF



Medicare Transaction Facilitator Live Now

The screenshot shows the MTF home page. The navigation bar includes 'Administration', 'DE/TPSE Enrollment', 'Manufacturer Dashboard', and 'Reports'. The 'Reports' tab is highlighted with a green box. Below the navigation bar is a search bar labeled 'Find analyses & more'. On the left sidebar, 'Dashboards' is highlighted with a green box. The main content area shows a 'Dashboards' section with a card for 'MTF-R-104-D Chains and Associated Stores'.

This screenshot shows the 'MTF-R-104-D Chains and Associated Stores Report' page. The report title is 'MTF-R-104-D Chains and Associated Stores Report' with a subtitle 'Created on Date:2025-10-10'. The page features several filter dropdowns: 'Chain Name (ID)', 'Store Number', 'Business State', 'Business City', and 'Business Zip Code', all currently set to 'All'. The report content area is currently empty.

The screenshot shows the 'Manufacturer Dashboard' with a table listing manufacturers. The table has columns for 'Manufacturer Name', 'Drug Name', 'Manufacturer ID', 'MTF PM participant', and 'Redacted Effectuation Plan'. Each row includes a 'Download' link for the 'Redacted Effectuation Plan' column.

Manufacturer Name	Drug Name	Manufacturer ID	MTF PM participant	Redacted Effectuation Plan
Bristol Myers Squibb	ELIQUIS	M001	Yes	Download
Janssen Biotech, Inc.	STELARA	M009	Yes	Download
Immunex Corporation	ENBREL	M002	Yes	Download
AstraZeneca AB	FARUGA	M004	Yes	Download
Boehringer Ingelheim	JARDANCE	M007	Yes	Download
Merck Sharp Dohme	JANUVA	M006	Yes	Download
Novo Nordisk Inc	NOVOLOG; NOVOLOG FLEXPEN; NOVOLOG PENFILL FIASP; FIASP FLEXTOUCH; FIASP PENFILL	M008	Yes	Download
Novartis Pharms Corp	ENTRESTO	M003	Yes	Download
Pharmacytics LLC	IMBRUVICA	M005	Yes	Download
Janssen Pharms	XARELTO	M010	Yes	Download

The screenshot shows the 'Invite a new user to the MTF' form. The form includes fields for 'Legal first name', 'Legal last name', and 'Work email'. The 'User type' dropdown is set to 'Dispensing entity'. The 'User role' dropdown is open, showing options: '- Select user role -', '- Select user role -' (selected), 'Authorized Signatory Official', 'Access Manager', and 'Staff End User'.



Medicare Transaction Facilitator Workflow



MFP Basic Payment Flow

Step 1: Pharmacy purchases the drug at retail price

Step 2: Pharmacy submits MFP claim to Medicare Part D plan

Step 3: Plan processes back reimbursement of MFP & dispensing fee, along with anticipated Standard Default Refund Amount (SDRA).

Step 4: Data received by the MTF & transmit it to manufacturer

Step 5: Manufacturer calculates MFP refund amount (e.g., WAC – MFP) & refunds the dispenser within 14 days.

- No refund is issued for claims that are 340B eligible, when the 340B ceiling price is lower than MFP.



Standard Default Refund Amount (SDRA)

Estimated Refund amount **to be paid** by manufacturer to the dispensing entity on an adjudicated prescription.

$$(WAC-MFP) \times \text{Quantity Dispensed} = \text{Standard Default Refund Amount}$$

Per CMS: “Assists the manufacturer in calculating a refund”

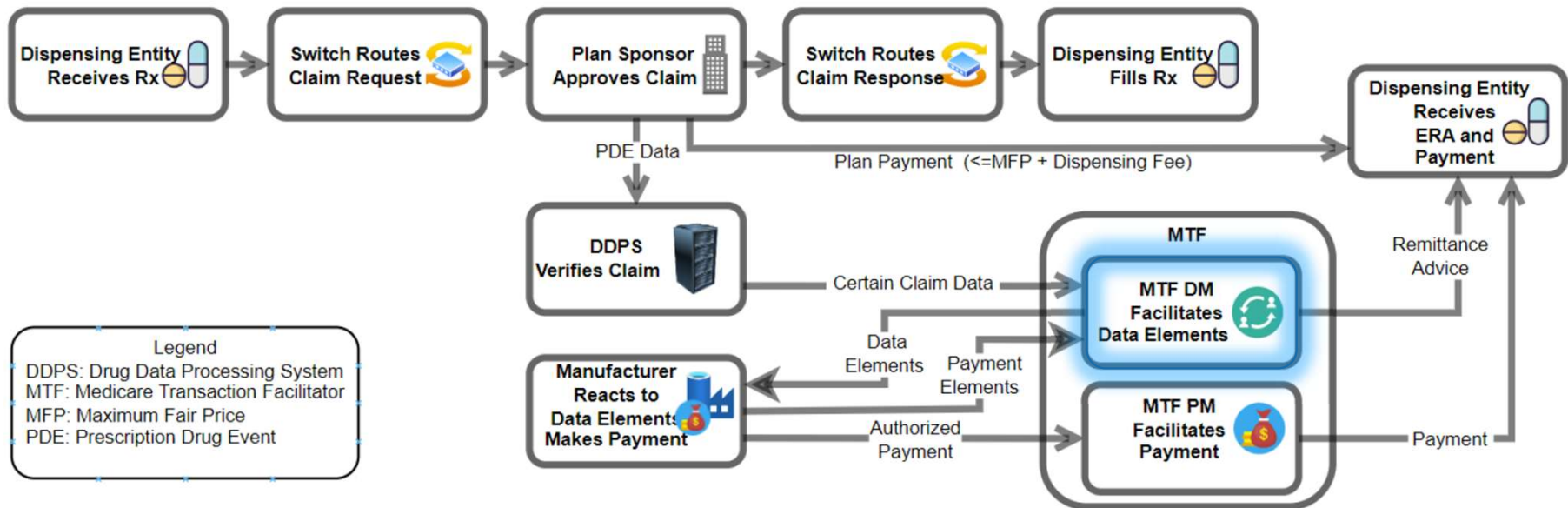
- Helps the pharmacy anticipate the amount due from manufacturer rebate for the prescription.

Claim 1

- Response Status Segment (21)
 - Transaction Response Status (AN) -- P
 - Authorization Number (F3) -- 251425182132453999
 - Additional Message Information Count (UF) -- 01
 - Additional Message Information Qualifier (UH) -- 38
 - Additional Message Information (FQ) -- 150.84



Medicare Transaction Facilitator (MTF) Data Flow



MTF DM Communication with Dispensers

MFP Claim Adjustment Reason Codes (CARCs):

- **307:** Medicare Maximum Fair Price Standard Default Refund Amount Adjustment. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code (RARC) that is not an ALERT.)

MFP Remittance Advice Remark Codes (RARCs):

- **N907:** No refund because this claim has been identified as 340B-eligible with a ceiling price lower than maximum fair price.
- **N908:** No refund because this drug has been prospectively purchased at the maximum fair price.
- **N909:** Refund amount has been calculated using a methodology that differs from the Standard Default Refund Amount calculation ((Wholesale Acquisition Cost minus Maximum Fair Price) times Quantity).
- **N910:** A refund cannot be provided for this claim at this time. **Contact the manufacturer** directly regarding your eligibility.
- **N911:** This claim cannot be reimbursed by the manufacturer until the Part D plan submits corrected prescription drug event data to CMS for maximum fair price validation. (Transmitted at 90 days)

To be used with the Medicare Drug Price Negotiation Program only.



IMBRUVICA® ADJUSTING WAC WHEN MAXIMUM FAIR PRICE (MFP) COMES INTO EFFECT WILL REMOVE ANY POTENTIAL REFUND DELAYS

imbruvica®
(ibrutinib)
420, 280, 140 mg tablets | 140, 70 mg capsules
70 mg/mL oral suspension

The assignment of an MFP for select drugs will change the drug reimbursement process, and DEs will have to wait for a manufacturer refund, the difference between WAC and MFP, after dispensing an MFP drug.

IMBRUVICA® intends to **adjust WAC to MFP** when MFP comes into effect on January 1, 2026¹. The manufacturer **refund will be zero**.

TWO SCENARIOS FOR CONSIDERATION

DE action items for effectuation**	WAC is greater than MFP	WAC is equal to MFP ¹
Await manufacturer refund after dispensing	Yes	No

Reducing the IMBRUVICA® WAC to the MFP removes the need for DEs to receive an MFP refund, which may result in less operational concerns and removes any potential for refund delays

^{*}This list is not exhaustive, and other DE action items may exist.
^{**}These action items are not mandatory and are only best practice suggestions.
¹When MFP comes into effect January 1, 2026.

 **AbbVie is committed to minimizing access barriers**

For more information about the IMBRUVICA® MFP, please email ImbruvicalRA@Abbvie.com

For more information on MTF enrollment and the Medicare Drug Price Negotiation Program, please review helpful resources for pharmacies and DEs directly from the CMS website here:
www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/pharmacy-and-dispensing-entity-resources

CMS may be contacted by **phone** at: 877-MTF-4HLP (877-683-4457) or **email** at: MFPMedicareTransactionFacilitator@cms.hhs.gov

It is important to note that CMS guidance is ongoing, and that many unknowns still exist. Information communicated on the website is subject to change in the future.

New Consideration Sales at MFP (RARC: N908)

340B Rebate Pilot 101



Inflation Reduction Act

“(d) NONDUPLICATION WITH 340B CEILING PRICE.—Under an agreement entered into under this section, the manufacturer of a selected drug—

“(1) shall **not be required to provide access to the maximum fair price** under subsection (a)(3), with respect **to** such selected drug and maximum fair price eligible **individuals who are eligible** to be furnished, administered, or dispensed such selected drug **at a covered entity** described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act **and the ceiling price** (defined in section 340B(a)(1) of such Act) **is lower than the maximum fair price** for such selected drug; and

“(2) shall be **required to provide access to the maximum fair price** to such covered entity with respect **to maximum fair price eligible individuals** who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price **if such maximum fair price is below the ceiling price** for such selected drug.”

136 STAT. 1842 PUBLIC LAW 117–169—AUG. 16, 2022



340B Rebate Model Pilot Program

Plan requirements:

- Ensure no additional administrative costs are passed to covered entities
- Provide 60 days' notice before implementation with instructions for registering for any IT platforms
- Maintain existing distribution mechanisms (e.g., 340B wholesaler accounts with pre-rebate prices loaded)
- Provide technical assistance & secure IT platforms for data submission, including HIPAA compliance
- Cannot deny rebates just for diversion or duplicate discount concerns
 - Rationales for claims denials may include deduplication for MFP or 340B rebate provided to another entity on the same claim



<https://federalregister.gov/d/2025-14619>
<https://www.hrsa.gov/opa/340b-model-pilot-program>



340B Rebate Model Pilot Selected Manufacturers

(Start Date: Jan 1st, 2026)

Manufacturer	Selected Drug Name	Contact email
Bristol Myers Squibb	ELIQUIS	Linda.kamin@bms.com
Immunex Corporation	ENBREL	340BRelations@amgen.com
Astra Zeneca AB	FARXIGA	340B@astrazeneca.com
Pharmacyclics	IMBRUVICA	340Brebateamodel@abbvie.com
Merck Sharp Dohme	JANUVIA	340Brebate@merck.com
Boehringer Ingelheim	JARDIANCE	340brebateamodel.rdg@boehringer-ingelheim.com
Novo Nordisk Inc.	NOVOLOG; FIASP	340binfo@novonordisk.com
Janssen Biotech, Inc.	STELARA	340B_JJHCS@its.jnj.com
Janssen Pharmaceuticals, Inc.	XARELTO	340B_JJHCS@its.jnj.com

[All Manufacturers have elected to use the Beacon platform](#)

340B Rebate Model Pilot Program

Plan limits data collection to the pilot approved elements listed:



Pharmacy Claims Data Fields	Medical Claims Data Fields
Date of Service	Date of Service
Date Prescribed	Claim Line Number
Rx number	Claim Number
Fill number	Unit of Measure
NDC-11	NDC-11
Quantity Dispensed	Quantity
Prescriber ID	Rendering Physician ID
Service Provider ID	Service Provider ID
340B ID	340B ID
RX BIN	Health Plan Name
RX PCN	Health Plan ID
Group Number ID (optional)	Health Plan ID Qualifier (optional)
	HCPCS Code (optional)
	HCPCS Modifiers (Up to 4) (optional)



New Pharmacy Payment & 340B Perspective

Element	Medicare Transaction Facilitator	Proposed 340B Rebate Pilot
Data Submission	Up to 7 days from Plan Sponsor to DDPS to MTF	Up to 45 days from CE to Rebate IT Platform
MFR Refund	14 Days	10 Days
Approximate Total	21 Day	55 Days
Refund Level	Unit	Unit Or Package (MFR determines)

Prospective 340B Claims Identification:

- Dispensing can **voluntarily include** a “340B Claim Identifier” (20) when submitting Part D claims through the MTF. This **signals** to manufacturers indicating the **claim is being billed for a 340B drug**.
- Once flagged, manufacturers review the claim data. If they reasonably determine the **340B ceiling price is lower than the MFP**, they **withhold the MFP refund** & log that decision in the claim-level payment records.

Retrospective 340B Claims Identification:

- CMS reiterated that it will “**continue to explore the feasibility** of incorporating 340B-related transactional data **from 340B covered entities or their third-party administrators (TPAs)** identifying claims eligible into MTF processes in the future,” including considering **incorporating asynchronous 340B data into the MFP validation procedures**.



340B Rebate Model Pilot FAQs: Who & Where

- **Which entities are subject to rebate pilot? Manufacturer may choose to include all covered entity (CE) types as part of their rebate models or limit to certain covered entity types. (Note: The 8 selected Manufactures have elected to include all CEs)**
- **Is rebate model only for drugs dispensed in retail? The 340B rebate pilot applies to all selected drugs under IPAY 2026 to the extent they are covered outpatient drugs, including physician- or clinic-administered drugs.**

<https://www.hrsa.gov/opa/340b-model-pilot-program>



340B Rebate Model Pilot FAQ: Selected Manufacturers

How will covered entities know which manufacturers are participating in the rebate model, what data they are requiring and for which drugs?

OPA will publish a summary of all approved rebate model plans on its website, prior to the plans' implementation. Additionally, **manufacturers are required to communicate details of their plans directly to covered entities** no later than **60 days prior to implementation** of their respective plans.

<https://www.hrsa.gov/opa/340b-model-pilot-program>



340B Rebate Model Pilot FAQs: Rebate Calculation

How are rebates calculated?

Rebates will be calculated as **WAC minus the 340B ceiling price on the date of dispense** (date of service). The date of dispense is used in lieu of purchase date due to the limitation of data submitted by covered entities for each rebate claim. As the pilot progresses, OPA will evaluate potential incorporation of certain purchase data.

<https://www.hrsa.gov/opa/340b-model-pilot-program>



340B Rebate Model Pilot FAQ: Unused Accumulations

What if there are unreplenished 340B accumulations in my accumulator after the implementation of the rebate model pilot?

Covered entities should **work to replenish accumulations made prior to the implementation of the 340B Rebate Model Pilot Program**. For accumulations that occurred that were **unable to be replenished** prior to January 1, 2026, please **refer to each manufacturer's notice** to covered entities on how those 340B ceiling prices will be effectuated.

<https://www.hrsa.gov/opa/340b-model-pilot-program>



340B Rebate Model Pilot FAQ: Wholesaler Orders

How should covered entities order 340B drugs subject to rebates? Covered entities **should only order drugs included in the 340B Rebate Model Pilot Program through their current 340B wholesale account**. Manufacturers, with approved 340B rebate models, will update price files with their **wholesalers** to appropriately **reflect the WAC price in the 340B account**, so that once the rebate is paid, the 340B ceiling price is effectuated. This will decrease burden on covered entities to place 340B orders to multiple accounts, create a standard rebate amount for all 340B purchases made through the rebate model, allow manufacturers some assurance that the appropriate pre-rebate amount was charged for drugs subject to rebates, and allow OPA to maintain visibility into drugs purchased as part of the 340B Program. Rebates should only be requested by covered entities after a purchase is made in the 340B wholesale account.

Covered entities should not order drugs on any other accounts (e.g. WAC account or GPO account) to the extent they want to request a rebate on that drug. This will help ensure compliance with the GPO prohibition and ensure that the rebate amount paid will result in the effectuation of the 340B ceiling price.

It should be noted that if there is not an approved 340B rebate model for a manufacturer in place, WAC should not be loaded into the 340B wholesale account, but rather the 340B ceiling price should be loaded into the 340B wholesale accounts.

<https://www.hrsa.gov/opa/340b-model-pilot-program>



340B Rebate Model Pilot FAQ: Reconciliation

Can you spell out what the reconciliation looks like? What protections are in place to ensure issues are resolved quickly?

Covered entities should have **access to the real-time rebate status of a claim**, so they **can easily reconcile claims submitted with rebates paid**. If a claim takes longer than 10 days for a rebate to be paid, covered entities and manufacturers should work to resolve the issue. If HRSA observes trends toward a manufacturer not paying rebates within 10 days of data submissions, OPA reserves the right to revoke the rebate model approval for that manufacturer.

<https://www.hrsa.gov/opa/340b-model-pilot-program>



340B Rebate Model Pilot FAQ: Late Rebates

What should I do if I do not receive a rebate within 10 days of submitting claims data?

Covered entities who are not receiving rebates within the 10-day timeframe after submitting complete and accurate data, should **first contact the manufacturer and IT platform vendor** to report concerns. If after attempting to work with the manufacturer a covered entity **cannot resolve the issue** with the manufacturer, the covered entity should email 340BPricing@hrsa.gov with the **details of its concern**. A manufacturer that is **consistently unable to timely resolve rebate** reimbursement issues **may have its participation in the pilot program revoked**.

<https://www.hrsa.gov/opa/340b-model-pilot-program>



340B Rebate Model Pilot FAQ: Auditable Records

How will compliance be tracked in the 340B rebate model pilot?

As with all 340B Program requirements, auditable records should be maintained for both covered entities and manufacturers and OPA will incorporate compliance with the rebate model in audits of both covered entities and manufacturers. **Covered entities are expected to maintain auditable records of purchases and rebate requests to ensure that only purchases made in the 340B wholesale account at the WAC price are subject to rebate requests.** Rebates may not be requested on purchases made at the GPO price. OPA and manufacturers have audit authority to review for covered entity compliance under the rebate model.

<https://www.hrsa.gov/opa/340b-model-pilot-program>



340B Rebate Model Pilot FAQ: Ceiling Price

How will covered entities know what the 340B ceiling price is at the time of dispense?

Participating manufacturers have committed to supplying a 340B ceiling price file for the covered outpatient drugs under the rebate model pilot. **This file will be available for download on the rebate model's IT platform.** The file may also be used to feed pharmacy billing systems to assist with sliding fees and Medicaid billing at acquisition cost. The 340B OPAIS pricing component is also available for verification of the accuracy of the manufacturer provided files.

<https://www.hrsa.gov/opa/340b-model-pilot-program>



340B Rebate Model Pilot FAQ: Medicaid

What acquisition cost should I use for Medicaid billing purposes?

While the upfront purchase will occur at WAC, the cost of a 340B eligible purchase is expected to be the 340B ceiling price, once the rebate is paid. Participating manufacturers have committed to supplying a 340B ceiling price file for the covered outpatient drugs under the rebate model pilot. This file will be available for download on the rebate model's IT platform. The file may be used to feed pharmacy billing systems to assist with Medicaid billing at acquisition cost. The 340B OPAIS pricing component is also available for verification of the accuracy of the manufacturer provided files.

Covered entities should work with state Medicaid agencies to determine best practices for billing.

<https://www.hrsa.gov/opa/340b-model-pilot-program>



OUR PRODUCT SUITE

340B Rebate Model

→ [LEARN MORE](#)

Enables the submission, validation and payment of 340B rebates to 340B covered entities. Users can monitor rebate status, perform reconciliations and access auditable records.

Beacon's customer support team provides dedicated technical assistance and resolves inquiries.

Maximum Fair Price (MFP) Rebate Solution

→ [LEARN MORE](#)

Enables dispensing entities to easily research MFP rebate validation and payment status, reference the basis of pricing and reconcile MFP rebate payments against account receivables.

Our customer support team is ready to help, including through an interactive good faith resolution center.

Beacon Channel Management

340B Rebates

Paid
\$100,000

+3% this Week

Total Rebates

80

+3% this Week

MFP Rebates

3 +2 this Week

73 +5 this Week

1,005 +2 this Week

Beacon MFP

(Entity-Owned Pharmacies Only)












Beacon MFP supports all aspects of dispensing entity MFP effectuation interactions with manufacturers, aiming to provide a transparent, efficient, & accessible process.

Service	Description
Payment Tracking	Eligibility validation, expedited payment processing
Good Faith Inquiry	Dispute resolution, ticketing, documentation, tracking
Communication Hub	Single point of contact for all MFP-related communications
Self-Service	FAQs, webinars, claim status lookup
Customer Support	Email, phone, live chat, 24/7 online / email support
Proactive Outreach	Updates, training, onboarding, procedural changes
Audit & Compliance	Audit notifications, documentation, compliance support
Resolution Center	Issue resolution, inquiry tracking, escalation to manufacturer



Beacon MFP vs. Data Module

There are differences and similarities between what data is available by accessing Beacon MFP and CMS's Data Module

	BEACON MFP 	DATA MODULE 
PROCESSING STATUS		
FINAL STATUS		
GOOD FAITH INQUIRIES		
PAYMENT AMOUNT		
COMPLAINTS		
BASIS OF PRICING		 (sometimes)
LEDGER BALANCES		





Cash payments are handled by the MTF's PM. Offsetting credits are reflected in Beacon MFP.

ICN	NPI	NDC	DOS	Validation Status	Processing Status	Basis of Pricing ¹	Payment Amount
1234567	12345678910	11111111111	1/6/2026	● Validated	Approved	WAC	\$112.05
1234568	12345678911	11111111111	1/7/2026	● Validated	Pending MTF Response	--	--
1234569	12345678912	11111111111	12/30/2025	● Date of Dispense	Rejected	--	--
1234565	12345678913	11111111111	1/8/2026	● Validated	Approved	Contract Price	\$212.14
1234564	12345678914	11111111111	2/1/2026	● Validated	Approved	340B	\$0

Cross-walking ICN to RX & Fill

Beacon 340B

(All Covered Entities)

Beacon 340B is expected to be used by all initial 340B rebate pilot manufacturers for 340B claim management and dispute resolution

- 340B entities interact with Beacon for claim submission, status tracking, good faith inquiries, claims disputes and process support.

Service/Feature	Description
340B Rebate Model Pilot Program	Enables 340B entities to register and submit rebate claims to access the 340B Ceiling Price.
Claim Identification & Deduplication	Supports processes for certifying 340B status and deduplicating claims, including checking claim status directly in Beacon.
Dispute Resolution Center	Permits DEs to submit good faith inquiries about 340B claims, such as disputes over 340B status, rejected claims, or payment amounts.
Resources	Provides access to overviews of manufacturer processes, webinars, & FAQs. Available by email, phone, and live chat support (typically Mon-Fri, 9AM-9PM ET), with 24/7 online/email access. Most inquiries are handled by Beacon staff; complex cases may be escalated to the manufacturer.
Customer Support	



A person wearing a white lab coat is holding a tablet computer. The tablet screen displays a dashboard with various financial charts, including a donut chart on the left, a bar chart on the right, and a smaller bar chart at the bottom. A pen is held over the tablet, pointing at the bar chart. In the background, a laptop screen also shows similar data visualizations. The scene is set in a professional or clinical environment, with a blue circular overlay at the bottom containing the text.

Rebate Model Impact



Wholesaler Impacts

Potential Loss of
Wholesaler
Discounts

PVP Sub-Ceiling
Pricing

Interest Cost for the
Increased Upfront
Pricing

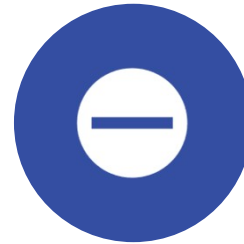
Change package
purchased to smaller
sizes may increase
overall price



Impacts to the Finance Team



Cost of Rebate Reconciliation



Missed Rebate Opportunities (Rebate Denials)



Loss Due to Waste/Expiration



Adjusting Financial Reports to Accurately Assess Profit/Loss

Impacts to the Entity- Owned Pharmacy Team



Time to Manipulate AAC for Medicaid Claims



Manually Maintaining a 340B Price File



Time to Reclassify Claims as 340B in Auditing & Recordkeeping

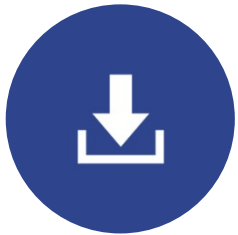


Time to Manually Adjust Pricing for Cash-Paying Patients





Impacts to the 340B Team



Time to Download
Reports from TPAs &
Adjusting CE ID



Time to Convert CAD
Logs from Paper to
Electronic



Manually Maintaining a
304B Price File



Time to Reclassify Claims
as 340B in Auditing &
Recordkeeping

MTF Financial Impact

Estimating MFP Impact on FQHC Entity-Owned Pharmacies

1. Pharmacy Claims Level Data

RX Number
Fill Number
Fill Date
Drug Name
Dispensed NDC
Dispensed Quantity
Inventory Tag
ACQ Cost
Total Ins Paid
Primary Ins Paid Amount
Primary Ins Name
Primary Ins BIN
Primary Ins PCN

2. CMS Resources for MFP

[CMS - MFP Drug NDC List](#)
[CMS - MFP Drug Negotiated Prices List](#)
[BINs & PCNs for Part D](#)

CMS.gov Centers for Medicare & Medicaid Services About CMS Newsroom Data & Research

Medicare Medicaid/CHIP Marketplace & Private Insurance Initiatives Training & Education

Initiatives Medicare Prescription Drug Affordability Overview Medicare Drug Price Negotiation Program Selected Drugs and Negotiated Prices

Overview

- Medicare Drug Price Negotiation Program
- Guidance and Policy Documents
- Selected Drugs and Negotiated Prices
- Public Engagement Events
- Medicare Transaction Facilitator General Resources
- Pharmacy and Dispensing Entity Resources
- Medicare Inflation Rebate Program
- Medicare Part D Improvements

Selected Drugs and Negotiated Prices

Negotiated Prices

[File for Negotiated Prices, also known as Maximum Fair Prices in Statute \(ZIP\)](#)

This file contains information on the negotiated prices under the Medicare Drug Price Negotiation Program, which the statute refers to as maximum fair prices (MFPs), for 10 drugs covered under Medicare Part D that will go into effect beginning January 1, 2026, based on negotiations and agreements reached between CMS and participating drug companies. The file contains the single negotiated price for a 30-day equivalent supply of each selected drug, NDC-9 per unit price, and NDC-11 per package price. The file also contains other important information regarding updates to the NDCs and MFPs.

The file is updated annually each year subsequent to the first initial price applicability year of the price applicability period for each selected drug, at a minimum, to show the inflation-adjusted negotiated price for the selected drug. Additional updates are made on a recurring basis to account for the application of the negotiated price to new NDC-11s of selected drugs or when an NDC-11 should no longer have the negotiated price applied. Lastly, additional updates are made to account for when a drug is no longer selected. CMS will publish the file in both .xlsx and .csv file formats.

Selected Drugs

[Selected Drug List \(ZIP\)](#)



Example Data for Estimating MFP Impacts

Drug Name	Dispensed NDC	Dispensed Quantity	ACQ Cost	Ins Paid Amount	Primary Ins Name	Primary Ins BIN	Primary Ins PCN
Humira Pen	74433902	12	\$207.72	\$37,132.92	D-Bcbs Mich-Medicare	610014	MEDDPRIME
Eliquis	3089321	180	\$61.71	\$1,826.54	D-Optumrx	610097	9999
Tradjenta	597014030	90	\$0.87	\$0.00	Cash Fp		
Entresto	78065920	60	\$317.04	\$321.64	D-Optumrx	610097	9999
Rinvoq Er	74230630	90	\$8,691.54	\$16,700.94	D-Express Scripts PDP	3858	MD

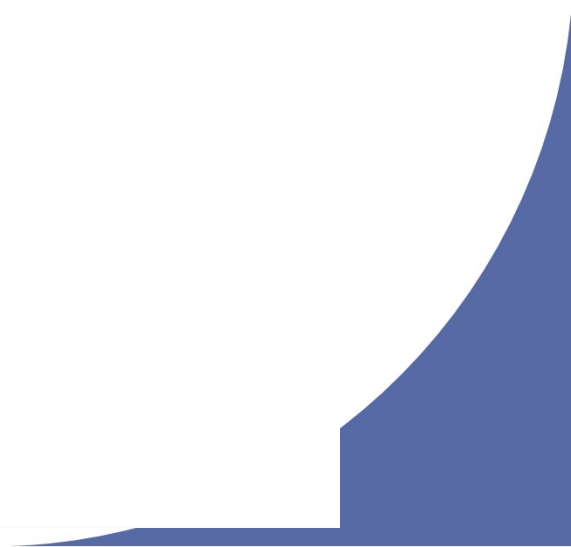
IRA Flag	Medicare Part D (Y/N?)	NDC-9 MFP Unit \$	MFP Price	MFP+0.5PDF	MFP+13.50PDF	SDRA	Non-MFP Claims	Total Ins Revenue (0.5)	Total Ins Revenue (13.50)
#N/A	Yes	#N/A	\$0.00	\$0.00	\$0.00	\$0.00	\$37,132.92	\$37,132.92	\$37,132.92
ELIQUIS	Yes	\$4.15	\$746.11	\$746.61	\$759.61	\$0.00	\$0.00	\$746.61	\$759.61
#N/A	#N/A	#N/A	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
ENTRESTO	Yes	\$5.23	\$313.60	\$314.10	\$327.10	\$3.44	\$0.00	\$317.54	\$330.54
#N/A	Yes	#N/A	\$0.00	\$0.00	\$0.00	\$0.00	\$16,700.94	\$16,700.94	\$16,700.94

Percent Difference		
Current Ins Reimbursement	\$55,982.04	0%
New Projected Ins Reimbursement Worst Case	\$54,898.01	-2.0%
New Projected Ins Reimbursement Best Case	\$54,924.01	-1.9%





MFP Impact on FQHC Entity-Owned Pharmacies



MFP Impact on FQHC Entity-Owned Pharmacies

MEDICARE IRA 2026 – AVERAGE PROJECTED REVENUE LOSS FROM MFP DRUGS			
No. of Pharmacies Analyzed	Medicare (%)	2026 Med D MFP Drugs as % of Rx Filled	Estimated Revenue Loss (%)
53	24.18 %	1.5%	9%

Estimated impact across pharmacies is approximately 10% loss in overall entity-owned pharmacy revenue



MFP Impact on CA FQHC Entity-Owned Pharmacies



MFP Impact on CA FQHC Entity-Owned Pharmacies

MEDICARE IRA 2026 – PROJECTED REVENUE LOSS FROM MFP DRUGS			
Pharmacy Size	Medicare (%)	2026 Med D MFP Drugs as % Rx Filled	Estimated Revenue Loss (%)
Small	10%	0.3%	2%
Medium	19%	1.3%	9%
Large	22%	1%	3%

Estimated impact across pharmacies in CA is approximately 5% loss in overall entity-owned pharmacy revenue



Switching to WAC: Inventory Cost Impact

FQHC ENTITY-OWNED PHARMACY ASSESSMENT

- Based on Quarter 3 pricing
 - Anticipate overall doubling of inventory cost by shifting initial 10 MFP drugs to purchase at WAC under rebate model
 - Cost for impacted NDCs was ~25x higher
- Based on the historical data at time of sale, WAC pricing was ~57x higher

INVENTORY COST OF CMS 30-DAY EQUIVALENT SUPPLY

Medication	Average of 340B Price per 30 DES	Average of WAC Price per 30 DES	Difference
ELIQUIS	\$8.89	\$563.15	\$554.26
ENBREL	\$0.04	\$8,232.53	\$8,232.49
ENTRESTO	\$547.14	\$1,202.85	\$655.70
FARXIGA	\$63.73	\$526.32	\$462.59
IMBRUVICA	\$6,065.43	\$15,915.44	\$9,850.01
JANUVIA	\$27.79	\$318.07	\$290.28
JARDIANCE	\$0.29	\$608.37	\$608.08
NOVOLOG; FIASP	\$77.25	\$321.15	\$243.90
STELARA	\$4,880.40	\$15,242.29	\$10,361.89
XARELTO	\$0.42	\$571.34	\$570.92



Dispensing Fees for Part D Negotiated Drugs

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE

DATE: August 25, 2025

TO: All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE Organizations

FROM: Vanessa S. Duran
Director, Medicare Drug Benefit and C&D Data Group

Lara Strawbridge
Acting Director, Medicare Drug Rebate & Negotiations Group

SUBJECT: Network Adequacy Requirements and Dispensing Fees for Selected Drugs

Under section 1860D-2(d)(1)(D) of the Social Security Act (the "Act"), as amended by section 11001(b) of the Inflation Reduction Act, Part D plan payment for a selected drug during its price applicability period must not exceed the applicable maximum fair price (MFP), plus any dispensing fees. When the MFPs are in effect beginning January 1, 2026, pharmacy reimbursement from Part D plan sponsors for dispenses of a selected drug will be no more than the selected drug's MFP (plus any dispensing fees). CMS has continued to hear concerns that pharmacies might be reimbursed by Part D plan sponsors below the price the pharmacy paid to acquire the selected drug, including potentially below the MFP for the selected drug. Many stakeholders have requested that CMS ensure Part D plan sponsors reimburse pharmacies at the MFP, plus a dispensing fee. As noted in CMS's October 2, 2024, [Medicare Drug Price Negotiation Program Final Guidance](#) for the second cycle of negotiation and manufacturer effectuation of negotiated MFPs in 2026 and 2027, the agency shares concerns raised in public comments regarding the potential impact on pharmacy revenue when MFPs for selected drugs take effect. CMS will closely monitor for whether further programmatic adjustments are needed to address any contrary practices that emerge.

CMS encourages Part D plan sponsors to work with their network pharmacies to ensure adequate and fair compensation for dispensing selected drugs. Specifically, we expect Part D plan sponsors' dispensing fees to sufficiently compensate network pharmacies so that enrollees can be assured network access to selected drugs. As defined at 42 C.F.R. § 423.100, dispensing fees

<https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-5-august-25-29>



Dispensing Fees for Negotiated Drugs

- Starting January 1, 2026, Part D plan payments for selected drugs must not exceed the drug's MFP plus any dispensing fees. **Pharmacies should be reimbursed at least the MFP plus a fair dispensing fee.**
- CMS is aware of concerns that pharmacies may be reimbursed below acquisition cost or MFP. The agency will monitor for any practices that undermine fair compensation & may adjust program requirements if needed.
- **Definition of Dispensing Fee:** Dispensing fees cover pharmacy costs beyond the drug's ingredient cost, including:
 - Salaries
 - Time for coverage checks
 - Filling containers
 - Packaging
 - Overhead (e.g., IT)
- **Network Adequacy Requirements:** Part D sponsors must ensure enough pharmacies participate in their networks to provide convenient access to covered drugs.





Cash Flow Concerns

Cashflow Concern Mitigation

Primary Manufacturer's MFP Effectuation Plan Must

- Include process for mitigating material cashflow concerns
- Address potential delays from retrospective MFP refunds
- Ensure compliance within the 14-day prompt MFP payment window

Process for Pharmacies to Self-Identify Cashflow Concerns

- Pharmacies most likely to be impacted include:
 - Sole proprietor rural or urban pharmacies with high Medicare Part D prescription volume
 - Pharmacies relying predominantly on Medicare prescription revenue
 - Long term care pharmacies
 - 340B entities with in-house pharmacies

MFR Effectuation Plans
Published in the MTF



Manufacturers Processes for Mitigating Material Cashflow Concerns for Dispensing Entities

Manufacturer & Drug	Summary of Response
AbbVie (Imbruvica)	Will monitor CMS-provided list of entities with cashflow concerns & consider mitigation steps via Beacon. Entities can request mitigation; AbbVie may modify effectuation timing as needed.
AstraZeneca (Farxiga)	Commits to SDRA calculation for payment, recognizes WAC pricing at claim adjudication, processes daily data transfers.
Boehringer Ingelheim (Jardiance)	Supports dispensing entities with cashflow concerns by relying on MTF DM/PM for timely, accurate data & daily payment submissions. Refunds expected within 23 days of claim submission, ahead of typical net-30 payment terms.
BMS (Eliquis)	Relies on MTF DM/PM for timely refunds; daily payment submissions; efficient processing to minimize cashflow concerns.
Immunex Corp (Enbrel)	Implements accelerated payment processing (target: 12 days) for all claims, not just those with self-identified cashflow concerns.
Janssen (Stelara & Xarelto)	Will effectuate MFP per CMS guidance, including cycle times for payment. Inquiry process for payment concerns; reconciliation via CMS processes.
Merck (Januvia)	Will dedicate extra resources in January 2026 for accelerated refund processing, aiming for faster timelines for all claims, especially those with cashflow concerns.
Novartis (Entresto)	Uses internal methodology to identify “Qualifying Cash Constrained Pharmacies” for expedited payment (7 days). Attributes include chain status, long-term care status, Part D volume variability, & distance to nearest pharmacy.
Novo Nordisk (Novolog-Fiasp)	Impact analysis concluded MFP rebates for Novolog/Fiasp will not cause material cashflow pressure for dispensers. Will consider legitimate inquiries & address as appropriate.



Additional requested content

- What to do now,
- next steps,
- do I need to hire someone. Or service?

FH1

Slide 64

- FH1** [@Logan Yoho] I know we have some of this somewhere...
Felicity Homsted, 2025-10-29T19:41:20.889
- LY1 0** I am not sure what you are looking for here. We may have something but I need a bit more to understand.
Logan Yoho, 2025-10-30T12:32:54.848
- FH1 1** reconciliation
Felicity Homsted, 2025-10-31T00:09:08.566
- FH1 2** Also it think we had some basic next steps slides for NACHC
Felicity Homsted, 2025-10-31T00:09:44.367
- FH1 3** Per Kevin if you use a PSAO for Reconciliation they will handle the MFP portion completely
Felicity Homsted, 2025-10-31T00:10:48.851
- LY1 4** Are the next 4 slides what you were thinking about?
Logan Yoho, 2025-10-31T12:02:56.966



Wholesaler Impacts

Potential Loss of
Wholesaler
Discounts

PVP Sub-Ceiling
Pricing

Interest Cost for the
Increased Upfront
Pricing

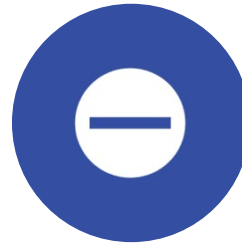
Change package
purchased to smaller
sizes may increase
overall price



Impacts to the Finance Team



Cost of Rebate Reconciliation



Missed Rebate Opportunities (Rebate Denials)



Loss Due to Waste/Expiration



Adjusting Financial Reports to Accurately Assess Profit/Loss

Impacts to the Entity- Owned Pharmacy Team



Time to Manipulate AAC for Medicaid Claims



Manually Maintaining a 340B Price File



Time to Reclassify Claims as 340B in Auditing & Recordkeeping

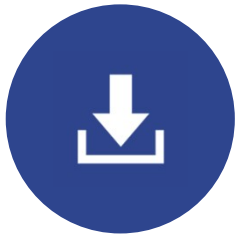


Time to Manually Adjust Pricing for Cash-Paying Patients





Impacts to the 340B Team



Time to Download Reports from TPAs & Adjusting CE ID



Time to Convert CAD Logs from Paper to Electronic



Manually Maintaining a 304B Price File



Time to Reclassify Claims as 340B in Auditing & Recordkeeping

Questions

Supplemental Slides

MTF DM Dispenser Enrollment

1. Entity User Roles

- **Authorized Signatory Official (AO)** - individual of the dispensing entity with authority to legally bind that organization in agreements
- **Access Manager:** designated by the AO may **view, modify, submit, & certify the completeness & accuracy of the information on this form & to submit complaints & disputes in the MTF DM on behalf of the organization.**
- **Staff End User:** designated by the Access Manager of the dispensing entity authorized to perform more limited tasks, such as view & download information in the MTF DM & submit complaints & disputes in the MTF DM on behalf of the organization.

2. Entity Identification Information

Option 1 (RECOMMENDED): Use the dispensing entity's information on the National Council of Prescription Drug Programs (NCPDP) to optimize MTF Data Module enrollment procedures.

Option 2: Manually enter information

- Legal Business Name
 - Doing Business As (DBA) Name
 - Store Location # (if applicable)
 - Mailing Address
 - Business Address
 - NCPDP "Provider ID"
 - Pharmacy National Provider Identifier (NPI)
 - State License Number (optional)
 - Federal Tax Identification Number
- **Opportunity to self-identify as anticipating material cashflow concerns** due to the shift from payment by the Part D sponsor to a combination of Part D sponsor payment plus a potentially lagged MFP refund.
 - Must provide NPIs for anticipated pharmacies



MTF DM Dispenser Enrollment

3. Entity Financial Information

Payments Direct to Entity:

- May choose electronic funds or paper checks
- The financial institution's name must be the legal business name of that financial institution.
- The account to which electronic transfer of funds payments is made must bear the account holder's name & legal business name.
 - Account number should include applicable leading zeros.
- Submit a **voided check or a letter on the bank's letterhead for verification** purposes.
- For Paper Checks:
 - Payment Address for remittance

Payments to Third Party Entity (e.g., PSAO):

- Will first elect to use a Third Party then select the name from a dropdown menu of third-party support entities listed in NCPDP
- Completed for both Payment Support & Remittance Advice

4. Refund Payment for MFRs Not using MTF Payment Module

- Dispensing Entity Acknowledgment of Information Sharing with Primary Manufacturers Not Using the MTF Payment Module.
- Confirmation of Dispensing Entity MFP Refund Payment Instructions to a Third-Party Support Entity.



MTF DM Dispenser Enrollment

5. Entity Contact Information

Primary & Secondary Point of Contact

- First Name
- Last Name
- Title
- Email Address
- Phone Number (1)
- Phone Number (2) Optional
- Should be **individuals who are knowledgeable** about the contents in this form & **able to respond any inquiries from CMS or the MTF** if clarifications or additional information is needed.

6. Entity Certification

An **individual eligible to certify** this submission on behalf of the dispensing entity **must be one of the following**: (1) the chief executive officer (**CEO**) of the organization, (2) the chief financial officer (**CFO**) of the organization, (3) an individual other than a CEO or CFO, who has authority **equivalent to a CEO or CFO** of the organization, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

Certification: I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I understand the information contained in this submission is being provided to and will be relied upon by CMS to facilitate payment of an MFP retrospective refund on MFP-eligible claims of selected drugs from the Primary Manufacturer to the dispensing entity in accordance with section 1193(a)(3) of the Social Security Act. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed.



Prescriptions Eligible For MFP Drugs: 2026-2027



Pharmacy Prescriptions

Dispensed under Medicare Part D by Retail, Specialty, Mail Order Pharmacy etc.

Individual enrolled in a prescription drug plan under Medicare Part D or MA-PD plan (including an Employer Group Waiver Plan)



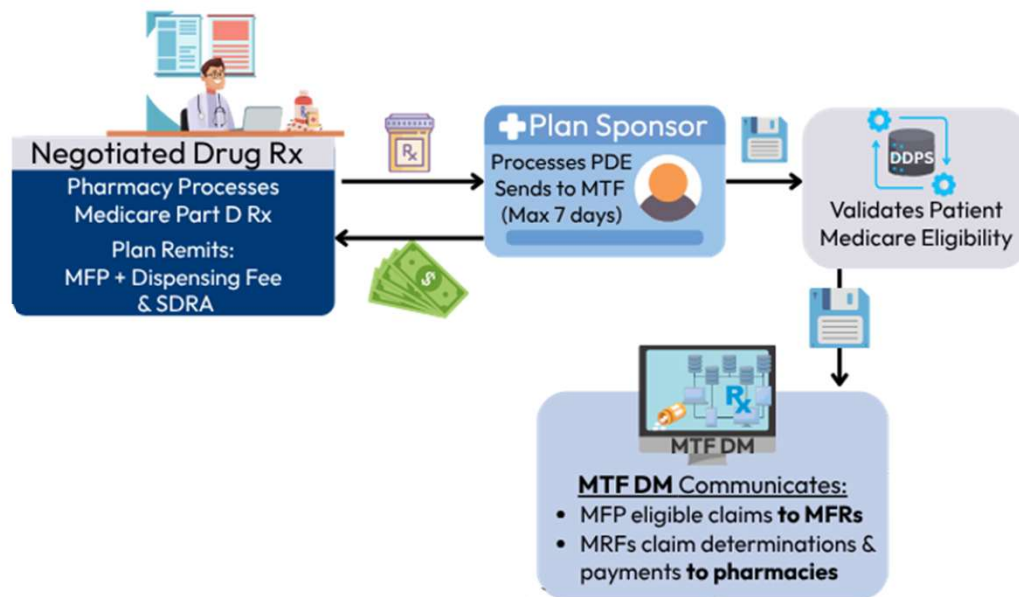
Physician Administered Drugs

For 2026-2027, CMS does not expect manufacturers to provide MFP on selected drugs to hospitals, physicians, & other providers for drugs administered to MFP-eligible individuals under Part B or MA plan



Step 1

- Pharmacy processes prescription, it is validated by the Plan Sponsor & Medicare Drug Data Processing System (DDPS), & then sent to the Medicare Transaction Facilitator (MTF)



Abbreviations

DDPS: Drug Data Processing System
MFP: Maximum Fair Price
MFR: Manufacturer
MTF: Medicare Transaction Facilitator
MTF DM: MTF Data Module
MTF PM: MTF Payment Module
PDE: Prescription Drug Event
RARC: Remittance Advice Remark Code
SDRA: Standard Default Refund Amount
WAC: Wholesale Acquisition Cost

*Graphic Created by
Felicity Homsted, PharmD, MBA, 340B-ACE
CEO| FQHC 340B Compliance



Step 2

- The Medicare Transaction Facilitator (MTF) communicates the MFP prescription information to manufacturers.
- Manufacturers determine within 14 days if claims are eligible for MFP refund or exempt due to 340B



Abbreviations

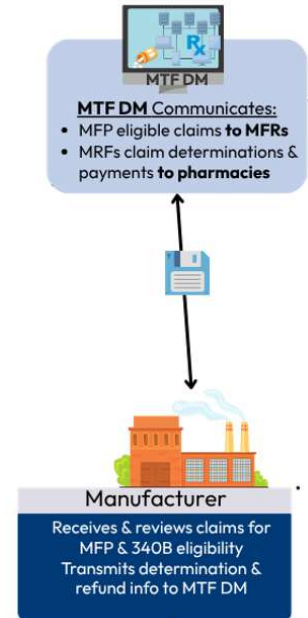
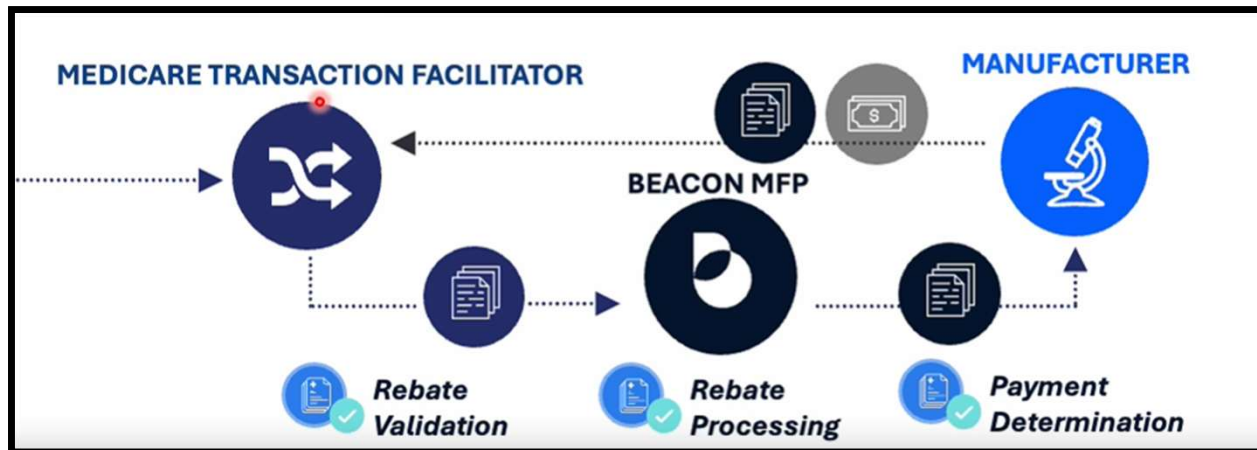
DDPS: Drug Data Processing System
MFP: Maximum Fair Price
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SDRA: Standard Default Refund Amount
WAC: Wholesale Acquisition Cost

*Graphic Created by
Felicity Homsted, PharmD, MBA, 340B-ACE
CEO| FQHC 340B Compliance



Step 2.5

- Manufacturers determine if claims are eligible for MFP refund or exempt due to 340B with the help of Beacon MFP
 - Beacon MFP will also support MFP good faith inquiries, & rebate claim disputes



Abbreviations
 DDPS: Drug Data Processing System
 MFP: Maximum Fair Price
 MFR: Manufacturer
 MTF: Medicare Transaction Facilitator
 MTF DM: MTF Data Module
 MTF PM: MTF Payment Module
 PDE: Prescription Drug Event
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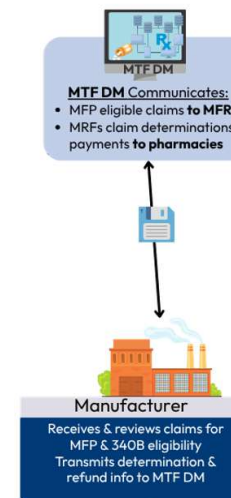
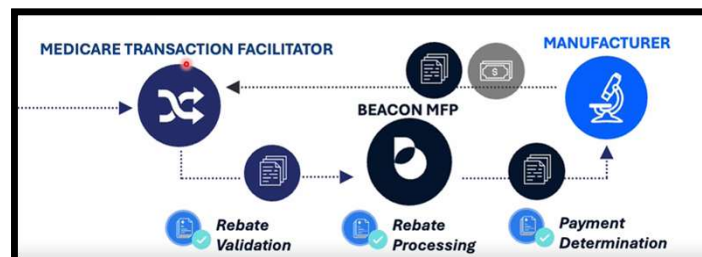
*Used with permission from Beacon Channel Management.
<https://mfp.support.beaconchannelmanagement.com/en/collections/15401063-beacon-mfp-on-demand-webinar-series>

*Graphic Created by
 Felicity Homsted, PharmD, MBA, 340B-ACE
 CEO| FQHC 340B Compliance



Step 2.5 Beacon MFP

- Manufacturers determine if claims are eligible for MFP refund or exempt due to 340B with the help of Beacon MFP



ICN	NPI	NDC	DOS	Validation Status	Processing Status	Basis of Pricing ¹	Payment Amount
1234567	12345678910	11111111111	1/6/2026	Validated	Approved	WAC	\$112.05
1234568	12345678911	11111111111	1/7/2026	Validated	Pending MTF Response	--	--
1234569	12345678912	11111111111	12/30/2025	Date of Dispense	Rejected	--	--
1234565	12345678913	11111111111	1/8/2026	Validated	Approved	Contract Price	\$212.14
1234564	12345678914	11111111111	2/1/2026	Validated	Approved	340B	\$0

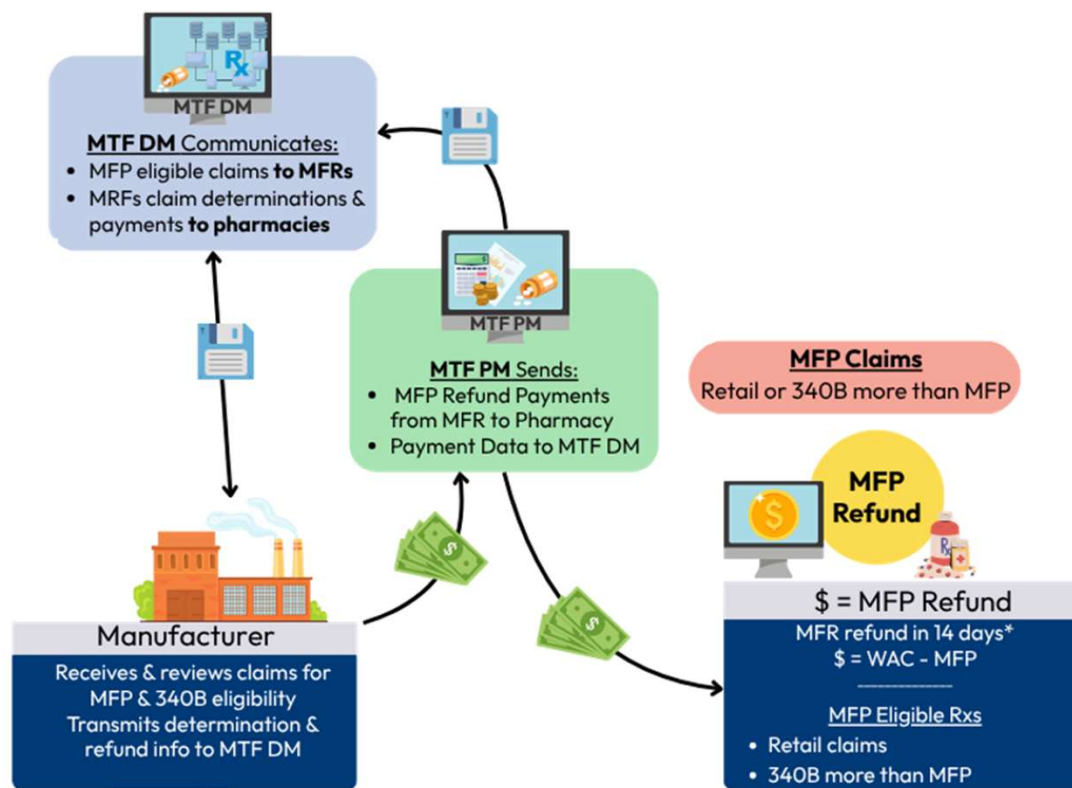
Cash payments are handled by the MTF's PM. Offsetting credits are reflected in Beacon MFP.

*Used with permission from Beacon Channel Management.
<https://mfp.support.beaconchannelmanagement.com/en/collections/15401063-beacon-mfp-on-demand-webinar-series>



Step 3: If MFP Eligible

- If MFP eligible, including when 340B Price is higher than MFP, manufacturer process payments through the MTF within 14 days



Abbreviations

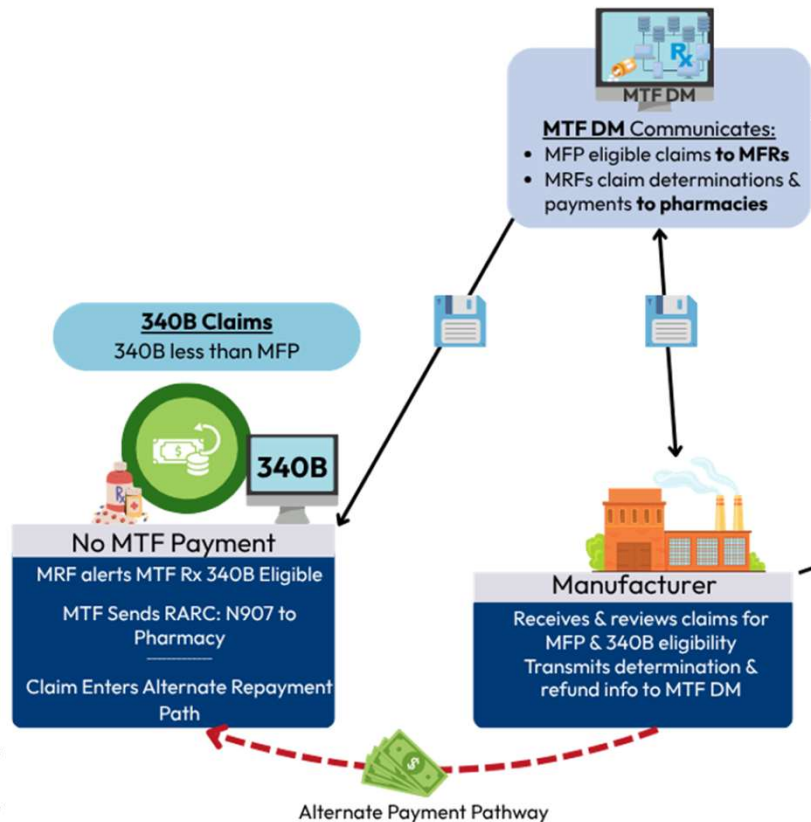
DDPS: Drug Data Processing System
MFP: Maximum Fair Price
MFR: Manufacturer
MTF: Medicare Transaction Facilitator
MTF DM: MTF Data Module
MTF PM: MTF Payment Module
PDE: Prescription Drug Event
RARC: Remittance Advice Remark Code
SDRA: Standard Default Refund Amount
WAC: Wholesale Acquisition Cost

*Graphic Created by
Felicity Homsted, PharmD, MBA, 340B-ACE
CEO| FQHC 340B Compliance



Step 3: If 340B Eligible

- If MFP ineligible (exempt) when 340B Price is lower than MFP, manufacturer will alert the MTF within 14 days.
 - MTF will alert dispenser in 835 file
- 340B eligible claims enter alternate payment pathway
 - To date, most manufacturers are electing to use Beacon 340B



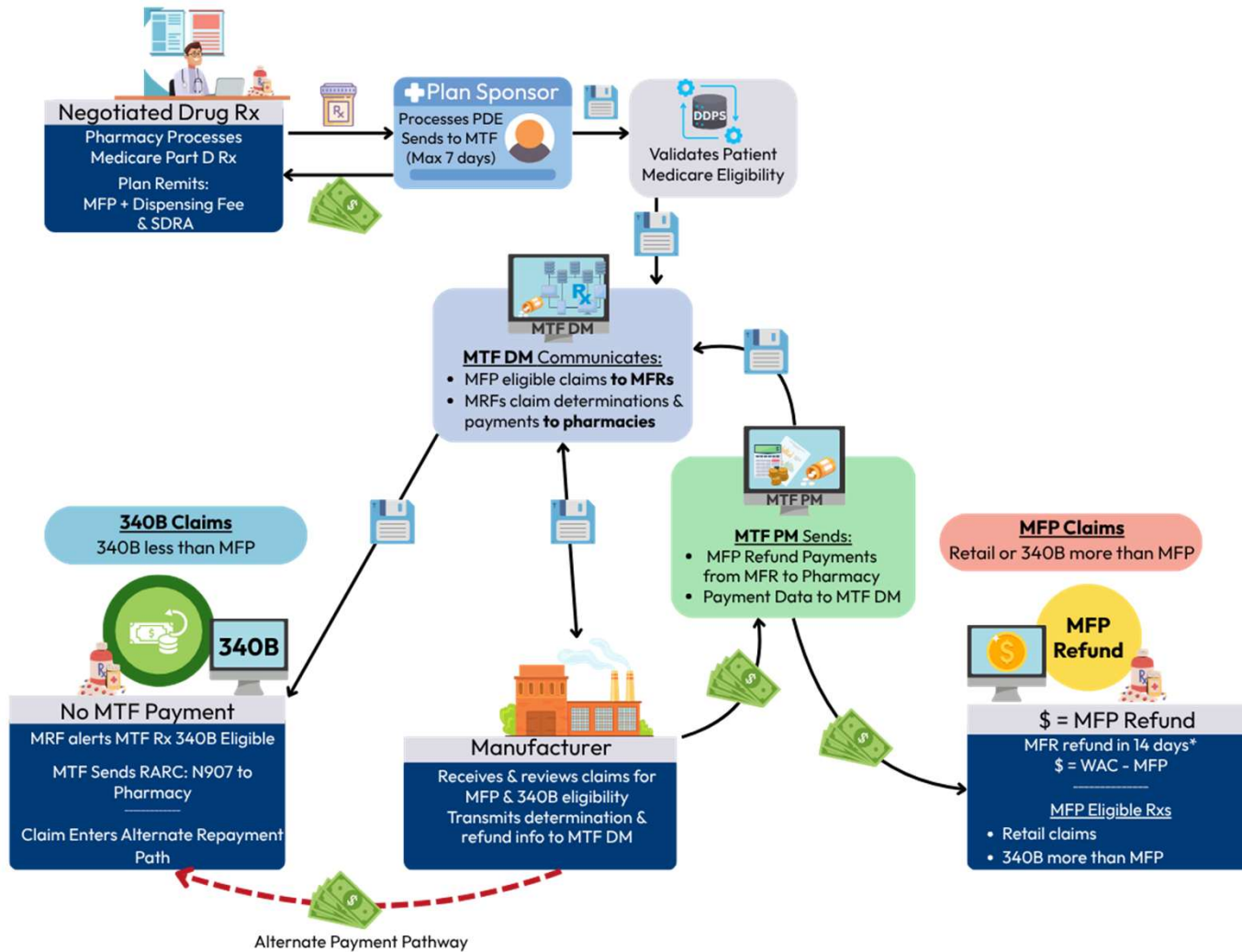
Abbreviations

DDPS: Drug Data Processing System
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 MTF DM: MTF Data Module
 MTF PM: MTF Payment Module
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 CEO| FQHC 340B Compliance



Medicare Transaction Facilitator Workflow



Abbreviations

- DDPS: Drug Data Processing System
- MFP: Maximum Fair Price
- MFR: Manufacturer
- MTF: Medicare Transaction Facilitator
- MTF DM: MTF Data Module
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FEDERAL REGISTER

The Daily Journal of the United States Government



The National Archives and Records Administration is closed to normal operations due to a lack of appropriations. FederalRegister.gov will automatically provide the daily Federal Register and Public Inspection List but we will not provide technical support. The official, published Federal Register is available at <https://www.govinfo.gov/app/collection/fr>.

 Notice

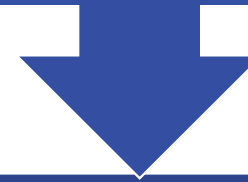
Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-0111-Extension

Rebate Model Impact ICR

A Notice by the Health Resources and Services Administration on 09/12/2025

What is an ICR?

An Information Collection Request (ICR) is a set of documents that describes **reporting, record keeping, survey, or other information collection requirements imposed on the public by a federal agency.**



What is covered in an ICR?

A description of the information to be collected

The reason the information is needed

An estimate of the time & cost for the public to answer the request.

Information Collection Request (ICR): 340B Rebate Model Pilot Program Application

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FEDERAL REGISTER The Daily Journal of the United States Government

Notice

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-0111-Extension

A Notice by the Health Resources and Services Administration on 09/12/2025

This document has a comment period that ends in 48 days. (11/12/2025) [VIEW COMMENT INSTRUCTIONS](#)

PUBLISHED DOCUMENT: 2025-17641 (90 FR 44197)

DOCUMENT HEADINGS

Department of Health and Human Services
Health Resources and Services Administration

AGENCY:
Health Resources and Services Administration (HRSA), Department of Health and Human Services.

<https://public-inspection.federalregister.gov/2025-17641.pdf?1757594714>

HRSA Notice of Information Collection

- 01** Necessity & utility of the proposed information collection for the proper performance of the agency's functions

- 02** Accuracy of the estimated burden

- 03** Ways to enhance the quality, utility, & clarity of the information collected

- 04** The use of the automated collection techniques or other forms of information technology to minimize the ICR burden

HRSA's 340B Pilot Model Burden Estimates

HRSA estimated total annual burden is approximately 1,518,688 hours, primarily from covered entities reporting claims data.

The estimated annualized burden hours for the ICR are summarized as follows:

340B Program Rebate Model Pilot Program Plan Submission:

- **Respondents:** 9 manufacturers
- **Responses per Respondent:** 1
- **Total Responses:** 9
- **Average Burden per Response:** 8 hours
- **Total Burden Hours:** 72 hours

Covered Entities Reporting Claims Data to Third-Party Platform:

- **Respondents:** 14,600 covered entities
- **Responses per Respondent:** 52
- **Total Responses:** 759,200
- **Average Burden per Response:** 2 hours
- **Total Burden Hours:** 1,518,400 hours

Monthly Purchase Reports:

- **Respondents:** 9 manufacturers
- **Responses per Respondent:** 12
- **Total Responses:** 108
- **Average Burden per Response:** 2 hours
- **Total Burden Hours:** 216 hours

Manufacturer Total Burden: 288 hours

Covered Entities Total Burden: 1,518,400 hours

****ONLY THE TIME BURDEN OF UPLOADING
DATA WAS CONSIDERED****

New 340B Rebate Pilot Information from the ICR

- OPA will collect sales data from drug manufacturers for evaluation of the pilot program
- Manufacturers will be required to submit data to the 340B Prime Vendor monthly to ensure program integrity & to provide transparency in the 340B Program.
 - Monthly submissions will provide better data for tracking 340B data & reduce lag time in assessing Program metrics.
 - The data submitted is being collected to support the assessment of the 340B Rebate Model Pilot Program.

340B[®]
Prime Vendor
PROGRAM
Managed by Apexus



COVERED ENTITIES

MANUFACTURERS

DISTRIBUTION

340B UNIVERSITY

HRSA FAQs

RESOURCE CENTER

[ABOUT 340B & PVP](#)

APEXUS ANSWERS

The PVP Supports the 340B Drug Pricing Program

The Prime Vendor supports the HRSA 340B Drug Pricing Program as a voluntary program for covered entities and manufacturers.





Most Favored Nations

Most Favored Nations

(Executive Order 14297)



PRESIDENTIAL ACTIONS

DELIVERING MOST-FAVORED-NATION PRESCRIPTION DRUG PRICING TO AMERICAN PATIENTS

Executive Orders | May 12, 2025

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose. The United States has less than five percent of the world's population yet funds around three quarters of global pharmaceutical profits. This egregious imbalance is orchestrated through a purposeful scheme in which drug manufacturers deeply subsidize their products to access foreign markets, and subsidize that decrease through exorbitant high prices in the United States.

The United States has for too long turned its back on Americans, who have paid the highest prices for both drug manufacturers and other countries. These entities

- Sec. 4. Enabling Direct-to-Consumer Sales to American Patients at the Most-Favored-Nation Price... to “facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers that sell their products to American patients at the most-favored-nation price.”
- Sec. 5. Establishing Most-Favored-Nation Pricing... ‘to bring prices for American patients in line with comparably developed nations.’

- <https://www.federalregister.gov/documents/2025/05/15/2025-08876/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients>
- <https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/>



Trump Rx

Find your medication

January 2026

For the lowest price.

Most Favored Nations: Direct To Consumer

- Manufacturers implementing direct to consumer (DTC) strategies:
 - Amgen
 - AstraZeneca*
 - Bristol Myers Squibb
 - Boehringer Ingelheim
 - Eli Lilly
 - EMD Serono*
 - Novartis
 - Pfizer*
- <https://trumprx.gov/>

<https://www.mintz.com/insights-center/viewpoints/2146/2025-10-07-pivotal-week-pharmaceutical-policy-trump-administration>
<https://www.mintz.com/insights-center/viewpoints/2146/2025-09-09-mintz-ira-update-disrupting-pharmaceutical-supply-chain>



Most Favored Nations & EO Tarriff Impact

- **Pfizer first to agree to MFN terms:**
 - Offer its portfolio of drugs at MFN prices to every state Medicaid program.
 - Offer some of its medications directly to consumers at a discounted cash price.
 - Invest \$70 billion into research & development while expanding domestic manufacturing in the US.
- **Astra Zeneca second to agree to MFN terms:**
 - Offer its portfolio of drugs at MFN prices to every state Medicaid program.
 - Offer medications directly to consumers at a discounted cash price.
- **EMD Serono third to agree to MFN terms:**
 - Offer discounted access to fertility medications through TrumpRx.gov.
 - Offer its fertility drugs at MFN prices to every state Medicaid program.
 - Invest in US manufacturing for the first time.
- **Other Impacts**
 - Gilead Sciences, Johnson & Johnson, Roche, Novartis, & Bristol Myers Squibb **announced multibillion-dollar investment** in manufacturing, research, & development.
 - Merck, Novo Nordisk, & Eli Lilly **expand efforts** in Delaware, North Carolina, & Texas with the aim of anchoring U.S. manufacturing.
 - Novartis, AbbVie, Amgen, Regeneron, & Abbott **announced plans to expand** their US-based manufacturing & facilities.
- **Executive Order 14272: Ensuring National Security & Economic Resilience Through Section 232 Actions on Minerals & Derivative Products**
 - Summarized: Reduce reliance on foreign suppliers, leverage tariffs, incentivize domestic production.
 - Translated into a threat of 100% importation tax on pharmaceuticals.

<https://www.whitehouse.gov/articles/2025/05/president-trump-is-bringing-drug-manufacturing-back/>

<https://www.whitehouse.gov/fact-sheets/2025/10/fact-sheet-president-donald-j-trump-announces-second-deal-to-bring-most-favored-nation-pricing-to-american-patients/>

<https://www.whitehouse.gov/fact-sheets/2025/10/fact-sheet-president-donald-j-trump-announces-actions-to-lower-costs-and-expand-access-to-in-vitro-fertilization-ivf-and-high-quality-fertility-care/>



Inflation Reduction Act: Medicare Inflationary Penalties

Medicare Inflationary Penalties Overview



Manufacturers whose prices increased faster than inflation must pay rebates to Medicare



Manufacturers that do not comply must pay civil monetary penalties of 125% of the rebate amount



Drugs discounted under the 340B Program are excluded from the inflation rebates



Separate strategies will be taken to identify 340B drugs billed to Medicare, so they may be excluded from the rebates

Medicare Part B & Part D Rebate Reporting & Invoicing Timelines

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



Exclusion of 340B Units from Medicare Part B Inflationary Penalties

Reduced Coinsurance for Certain Part B Rebatable Drugs Under the Medicare Prescription Drug Inflation Rebate Program



Applicable July 1 – September 30, 2024

President Biden's historic Inflation Reduction Act requires drug companies to pay rebates to Medicare when prescription drug prices increase faster than the rate of inflation for certain drugs furnished to people with Medicare. This new inflation rebate applies to Medicare Part B rebatable drugs, which are single source drugs and biological products, including certain biosimilar biological products, beginning January 1, 2023.

HCPCS Code	Short Description	Inflation-Adjusted Coinsurance Percentage (Normally 20.000%)
Q2055	Abecma	19.96%
J0401	Abilify Maintena	19.92%
J0558	Bicillin C-R	14.54%
J0561	Bicillin L-A	14.95%
J0897	Prolia	18.49%

As of January 1, 2025: 340B covered entities must report the **“TB”** modifier on claim lines for 340B-priced drugs billed to Medicare Part B

<https://www.cms.gov/files/document/reduced-coinsurance-certain-part-b-rebatable-drugs-july-1-september-30-2024.pdf>
<https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf>



Medicare Part D Inflationary Drug Penalties: Voluntary 340B Claims Repository



340B Claims Repository Accelerated:

- Starting Fall 2026
- Exclusion of 340B units
- Initially proposed to start in 2028, then January 2026

Key Aspects Claims Repository

- Covered entities to submit 340B-identified Part D claims data
- Stores data elements, no 340B status verification by CMS
- Attestation of data accuracy required by CE
- Data matched to PDE records; matched units excluded
- Data must be submitted 90 days from close of quarter

For Future Rulemaking

- Potential for covered entities & 340B TPAs to report
- Support for leveraging existing data sources
- Minimize burdens on covered entities
- "CMS welcomes engagement with interested parties"

Five Data Elements :



Date of Service



Prescription Number



Fill Number



Pharmacy NPI



NDC

