# 340B Education

Medicare Transaction Facilitator: What you need to know



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## Medicare Transaction Facilitator (MTF)

- Enrollment begins June 9<sup>th,</sup> 2025
  - CMS will send invitation emails from June 8<sup>th</sup> - July 1<sup>st</sup> \*
- All Medicare Part D dispensers must enroll
  - Contractual provision & payment mechanism
- The MTF interfaces with NCPDP to help facilitate enrollment
- You-Tube videos available
  - https://www.youtube.com/watch?v=xrGOvqlfLcQ
  - https://www.youtube.com/watch?v=AUebtiiuD1M





### MTF Data Module **Enrollment** Phase

CMS anticipates enrolling pharmacies and other dispensing entities in the MTF DM **beginning in June 2025** 

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 (coming Fall 2025)





### MTF Data Module <u>Implementation</u> 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

#### Resources

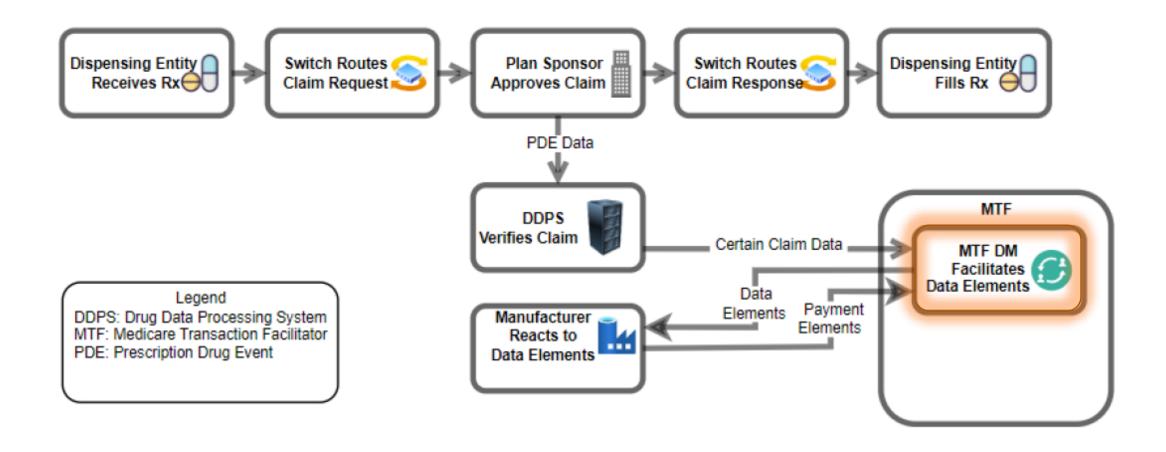
Medicare Transaction Facilitator: Fact Sheet for Pharmacies and Other Dispensing Entities (PDF) (April 7, 2025)

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



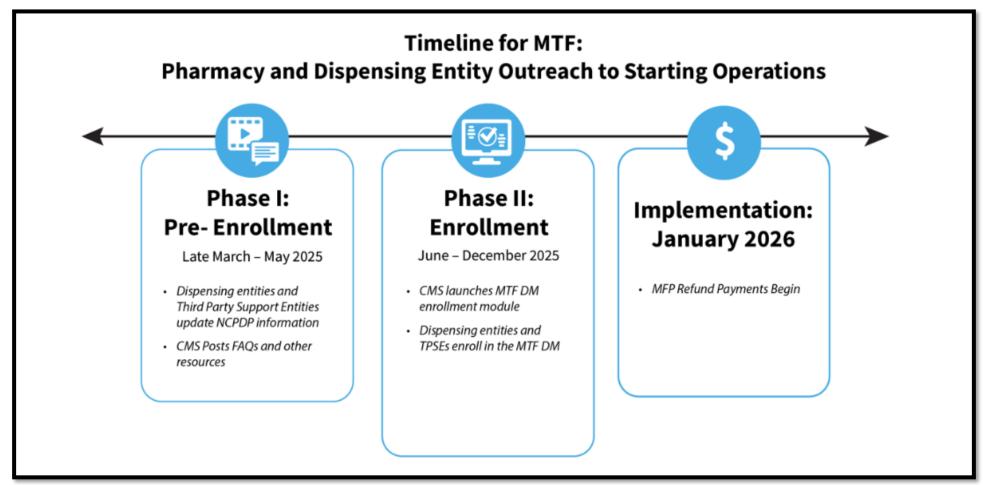


### **MTF Data Flow**





### MTF DM Pharmacy Enrollment Timeline



The CMS webinar on enrolling in the MTF is Thursday, June 5, 2025, from 1:00 PM to 2:30 PM EST.

The Webinar will be recorded and accessible after the event.

### 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, and certify the completeness and accuracy of the information on this form and to submit complaints and 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 and download information in the MTF DM and submit complaints and disputes in the MTF DM on behalf of the organization.

### 2. Entity Identification Information

**Option 1 (RECOMMENDED**): Use the dispensing entity's information to 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 and 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 and 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 and 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.





## 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 Due Sept 1<sup>st</sup>, 2025

## MFP Basic Payment Flow

- Step 1: Pharmacy purchase the drug at retail price
- Step 2: Pharmacy submits MPF 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 340 eligible, when the 340B ceiling price is lower than MFP.

## Standard Default Refund Amount (SDRA)

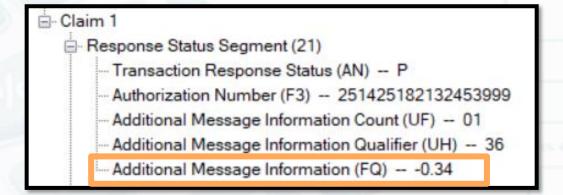
**Estimated Refund** amount **to be paid** by manufacturer to the dispensing entity on an adjudicated prescription.

(WAC-MFP) x Quantity Dispensed = 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.





## MFP Payment Flow Logistics

- Part D plans have 7 days to submit complete Prescription Drug Event (PDE) records to Drug Data Processing System (DDPS).
  - In recent rulemaking, CMA updated to shorten from 30 days for MFP drugs to facilitate more timely payment of MFP refunds.
- The MTF DM's transmission of the claim-level data elements to the Primary Manufacturer starts the 14-day prompt MFP payment window
  - The date of transmission of the claim-level data elements from the MTF DM to the Primary Manufacturer is considered day 0 of the 14-day prompt MFP payment window.
  - If a retrospective refund is required to effectuate the MFP, the Primary Manufacturer must transmit payment no later than 11:59 PM PT on day 14.



### 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 **differ**s from the <u>Standard Default</u> <u>Refund</u> 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.

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



## MFP & 340B Pricing

### Dispensers will be reimbursed at 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
  - <u>Duplication of discounts need to be prevented for 340B, Medicaid, and Medicare</u>
- If MFP sets a new "Best Price" there maybe up to a 2 quarters until seen in 340B price, due to calculation lag time.



### Voluntarily 340B Claims Identification

- Beginning January 1, 2025, the "Submission Clarification Code" value of "20" and the "Submission Type Code" value of "AA" will be added to the PDE record to indicate a 340B claim.
  - In NCPDP Telecommunications Standard F.2 and higher, the **340B value** has a new field: "Submission Type Code" and new value: "AA".
  - A dispensing entity may voluntarily apply these indicators to a Part D claim to indicate the claim is being billed for a 340B drug.
- The MTF's provision of the "340B Claim Indicator" data element does not represent or imply that CMS verified the 340B status of the claim nor that dispensing entities are required to include this code on claim submissions.



## Initial 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



## 15 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	Bristol-Myers Squibb	Oncology
Tradjenta	Boehringer Ingelheim/ Lilly	Diabetes
Trelegy Ellipta	GlaxoSmithKline	Asthma & COPD
Vraylar	Allergan	Antipsychotic
Xifaxan	Bausch & Lomb	GI Indications
Xtandi	Astellas	Oncology

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

By Michael Erman







https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10387900/pdf/jmcp.2023.29.3.229.pdf



## Prescriptions Eligible For MFP Drugs: 2026-2027





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, and other providers for drugs administered to MFP-eligible individuals under Part B or MA plan





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## **Contact Information**

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