

# IRA: An update on MFP implementation

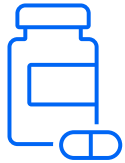
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Head of Market Access

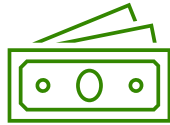
Pharmacyclics, A division of AbbVie

# IRA Reimbursement Model Introduction

## Background



In August 2023, CMS selected 10 drugs for the IRA “Medicare Drug Price Negotiation Program,” including Imbruvica



On August 15, 2024, CMS published the final Medicare prices for each selected drug, what CMS calls a “Maximum Fair Price” (MFP), effective on **January 1<sup>st</sup>, 2026**

- The Imbruvica MFP is \$9,319.00 per 30-day supply; each NDC has its own MFP based on average Rx days of supply



CMS has indicated that pharmacies dispensing Part D drugs will move from an AWP based reimbursement model to an **MFP based reimbursement model**

- CMS has indicated that they will closely monitor reimbursement to ensure adequate reimbursement for MFP drugs



**Manufacturers are responsible for making the MFP available** to dispensing entities, but the law does not mandate an exact instruction for implementation



AbbVie is in the process of comprehensively **evaluating potential mechanisms to operationalize MFP** in the market and are concurrently **considering the needs of our pharmacy partners**



# CMS Final MFP Effectuation Guidance

On October 2, 2024, CMS released final guidance on MFP Effectuation

Final CMS guidance **provided** new information in three key areas:



**1** Operations:  
Medicare Transaction Facilitator (MTF)



**2** Cash flow



**3** Reimbursement



The objective of this deck is to **summarize and communicate key points** from the final guidance



It is important to note that **CMS guidance is ongoing**, and that many unknowns still exist



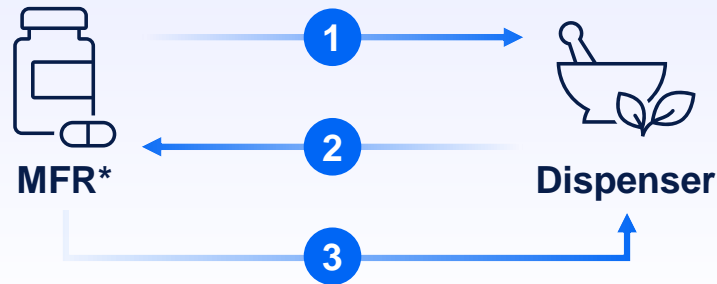
AbbVie is **committed** to fostering transparency and partnering with stakeholders as information evolves



# Medicare Transaction Facilitator (MTF)

How will MFP be made available to the Dispenser?

## Retrospective Model Simplified



- 1 **Dispenser buys\*** inventory at **WAC** less any contracted discounts
- 2 **After Rx** for Medicare patient, **claim data** is sent back† to MFR for **review & validation**
- 3 Manufacturer pays† "**MFP refund**"‡ to Dispenser

\*Purchase may be from Wholesaler depending on Dispenser's distribution network

†See next slides for more detail on claim and payment transmission

‡See slide 10 for more details on MFP refund calculation

AbbVie/PCYC intends to make Imbruvica's **MFP** available to Dispensers via a **Retrospective** model in 2026

While CMS Guidance allows for the possibility of a **Prospective** model where accounts purchase product at MFP, AbbVie determined the Retrospective model had the following advantages:

- ✓ **Streamline dispenser inventory:** Prospective model would require complex segregated virtual inventory
- ✓ **Less administrative burden:** Prospective model may require a higher volume of reversals, adjustments, and periodic true-ups



# Medicare Transaction Facilitator (MTF)

How will claims and payments be passed back and forth between Manufacturer and Dispenser?

## MTF Data Module

- ✓ **Mandatory** for Manufacturers
- ✓ Acts as a **data exchange** between Manufacturers and Dispensers
- ✓ Processes **MFP claims** from Plan and **claim responses** from Manufacturer
- ✓ CMS has awarded the MTF DM contract to **Data Computer Corporation of America (DCCA)**

## MTF Payment Module

- ✓ **Optional** for Manufacturers
- ✓ Acts as a **payment facilitator** from Manufacturers to Dispensers
- ✓ **Processes payments and sends remittance advice** from Manufacturer to Dispenser
- ✓ CMS has awarded the MTF PM contract to **National Government Services (NGS)**
  - **AbbVie is evaluating** options (including MTF PM) to make payments to Dispensers as simply, efficiently, and reliably as possible



# Medicare Transaction Facilitator (MTF)

What does a Dispenser need to do to engage the MTF?

## Requirements from Guidance

- 1 Execute an agreement\*** with CMS and MTF
  - Data security & documentation requirements
- 2 Enroll†** with MTF DM
  - Provide MTF banking information & payment receipt preferences

## Preparations Suggestions

- 3 New accounts receivable itemization**
  - To account for both Part D Payer reimbursement and new “MFP refund” receivable
- 4 Potential MTF Platform Testing**
  - CMS intends to **invite input and test** the MTF DM portal ahead of January 2026

Review draft\* MTF agreements at:  
<https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation>

\*Agreements are open for comment and subject to change

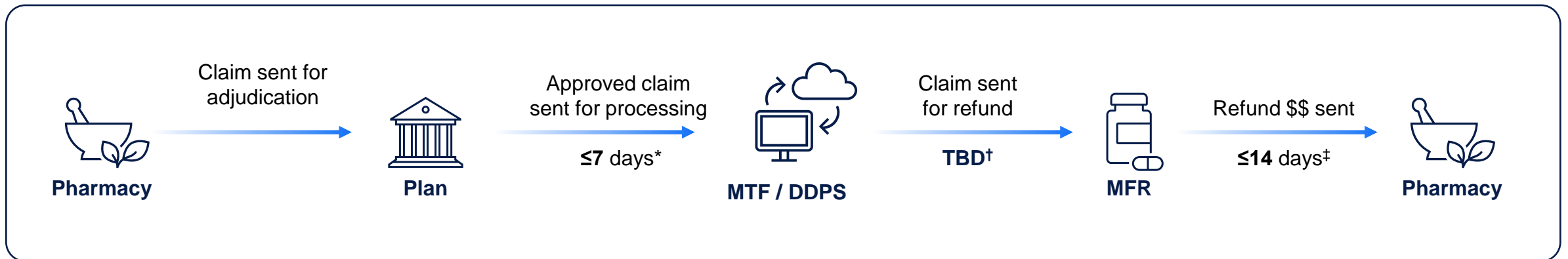
†CMS has not yet released comprehensive enrollment instructions



# Cash Flow & Reconciliation

How long will it take to be reimbursed in a Retrospective Model?

- During enrollment, Dispensers can self-identify as anticipating having **cashflow concerns** due to reliance on retrospective MFP refunds within the 14-day prompt payment window
- An example illustration of the **Retrospective refund timeline** is below. AbbVie is exploring potential options to **minimize time until payment** while maintaining processes essential to ensuring data integrity



\*CMS has indicated they will implement formal requirement for plans to transmit claim within 7 days

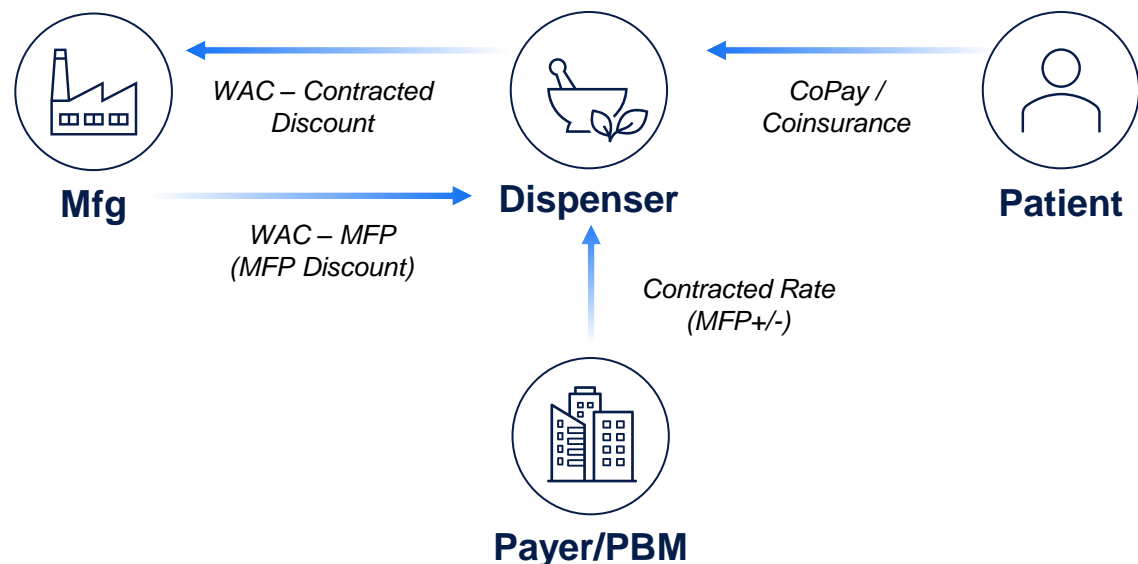
†CMS has not indicated how long validation by its internal DDPS system will take

‡Manufacturer must send confirmation of payment 14 calendar days from receiving claim



# Reimbursement

What can pharmacies expect in terms of cost recovery?



In final guidance, CMS **did not establish requirements for reimbursement or dispense fees**; however, CMS **stated**:

- ✓ “CMS will work to ensure plans and PBMs engage in **sustainable and fair reimbursement** practices with all pharmacies to ensure access to selected drugs”
- ✓ “CMS intends to **closely monitor** plan reimbursement for selected drugs including pharmacy price concessions”
- ✓ “CMS may take **immediate steps** to ensure **adequate reimbursement** for, and access to, selected drugs as needed”

**Based upon current CMS guidance and operational considerations, to the extent a refund is due, AbbVie intends to calculate the MFP refund for Imbruvica at WAC-MFP rather than Acquisition Cost-MFP**





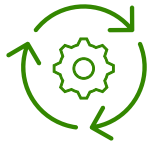
# Key Takeaways



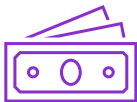
MFP does not take effect **until January 1<sup>st</sup>, 2026**



Starting January 1<sup>st</sup>, 2026, **MFP will be made available** to Dispensers for Imbruvica dispenses to Medicare patients



The primary **operational changes** for Dispensers to receive MFP: sign agreement, enroll with CMS/MTF, and itemize 2 reimbursements



AbbVie is exploring potential options to **minimize the 14-day prompt payment** window



**CMS** guidance mentioned **sustainable MFP Payer reimbursement** to dispensers



AbbVie/PCYC have **not yet finalized** an **effectuation** solution and will have forthcoming communication with final details

AbbVie/PCYC intends to effectuate MFP through **retrospective** reimbursement and calculate MFP refund as **WAC-MFP** rather than **Acq. Cost-MFP**



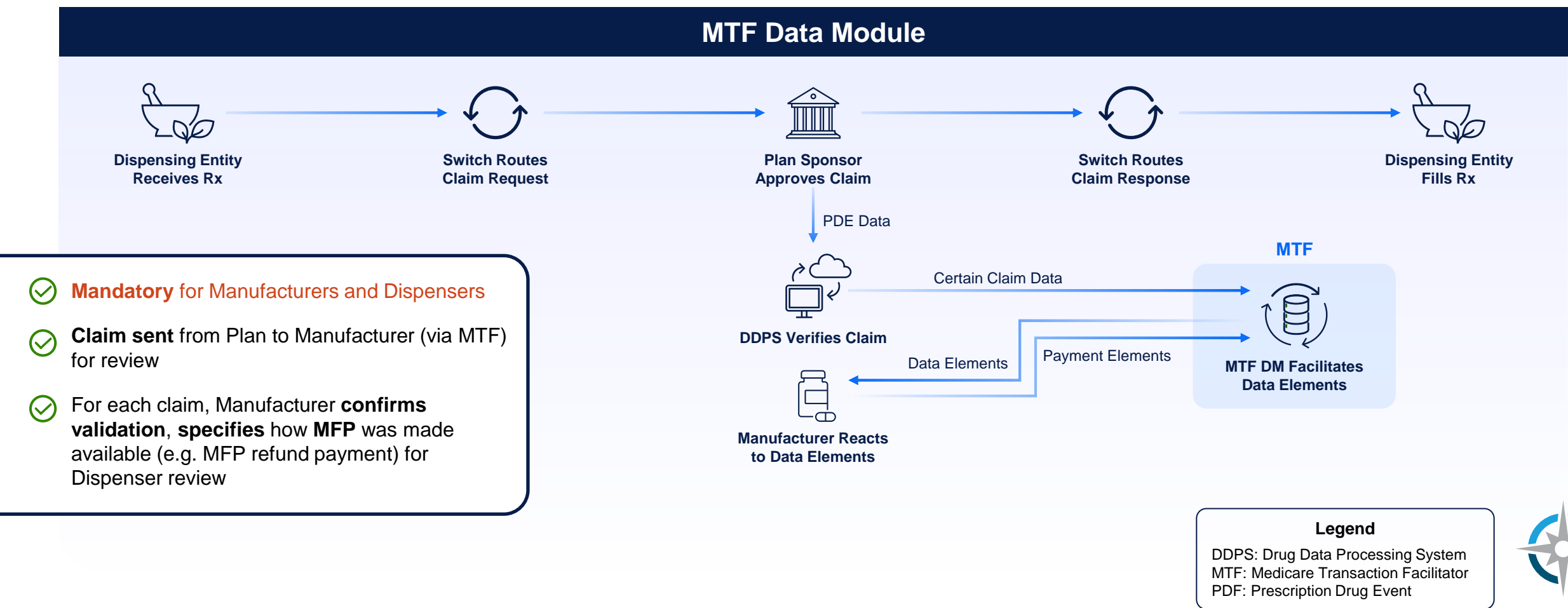
AbbVie/PCYC is committed to considering the **economic and operational needs** of our **dispensing partners** and fostering **simplicity & transparency**



# Appendix

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