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Latest From the Implementation of the Inflation Reduction Act: M3P, MFP, and IRA

NCPA 2024 Annual Convention and Expo

Columbus, Ohio

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Pharmacist and Technician Learning Objectives

1. Define the key components of the Medicare Prescription Payment Plan (a.k.a. MPPP, M3P).
2. Describe the potential impact of the Medicare Prescription Payment Plan on pharmacy workflows.
3. Discuss the potential impact of the Medicare Drug Price Negotiation Program on pharmacy operations.
4. Outline the revenue cycle for prescriptions reimbursed at Maximum Fair Price.

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Raise your hand if you know about more than two of these:

- IRA
- MDRNG
- MPPP
- MFP
- MTF

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Raise your hand if you know about more than two of these:

- IRA- Inflation Reduction Act
- MDRNG- Medicare Drug Rebate Negotiation Group
- MPPP – Medicare Prescription Payment Plan
- MFP – Maximum Fair Price
- MTF- Medicare Transaction Facilitator

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Inflation Reduction Act

2023

- Vaccines – Part D, Medicaid, CHIP
- Insulin – Part D and MA

2024

<u>For Part D:</u>

- Coinsurance for catastrophic coverage eliminated
- Premium increases capped

2025

<u>For Part D:</u>

- Annual out-of-pocket cap
- Optional “smoothing” of patient cost-sharing

2026

- Medicare Part D drug price negotiation

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Medicare Prescription Payment Plan highlights

- Part D Plans are required to offer the Medicare Prescription Payment Plan.
- MPPP (sometimes M3P) is *brand new* for 2025.
- #1 is to help Medicare patients afford the cost of prescription drugs.
- Greatest benefit is to patients with high drug costs early in the year.
- Must be a Part D covered drug.
- Also new for 2025, the maximum out-of-pocket cost is $2000.

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Medicare Prescription Payment Plan key components

- The Medicare Prescription Payment Plan is completely optional for patients.
- Part D Plan members need to opt-in.
- Certain claims will trigger a requirement that the pharmacy give the patient a standard notice about MPPP.
- Opt-in can happen at any time, as can opt-out.
- Patients pay $0 at the pharmacy, but will get a monthly bill from the Part D Plan.

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Medicare Prescription Payment Plan in the pharmacy workflow

Scenario 1: the patient already opted in

- The MPPP will function like a new insurance for the patient profile.
  - CMS requires that the PCN always begins with “MPPP”.
  - Paid claim responses will have MPPP processing information in the claim detail information “Coordination of Benefits/Other Payers” segment.
  - NOTE: MPPP processing information will NOT be in the E1 eligibility response.
  - Submit the claim to the Part D plan, any secondary insurance, and then the MPPP.
  - The patient pays $0 at the pharmacy counter.
- Copays for unsold prescriptions in will call should be processed to MPPP if the patient opts in.
- Prescriptions *already* sold to the patient do not need to be reprocessed.

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Medicare Prescription Payment Plan in the pharmacy workflow

Scenario 2: the patient is not opted in

- If a claim comes back with a copay >$600, there will be an Approved Message Code from the plan flagging that the patient is likely to benefit from MPPP and the pharmacy should give the patient a paper copy of a standardized notice.
- The patient will choose whether to opt in before the prescription is sold and may return after opting in.
- After opting in, all unsold prescriptions must be submitted to the MPPP.

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Medicare Prescription Payment Plan revenue cycle

- Reimbursement to the pharmacy is the same 14-day timeframe whether it is the primary Part D claim or the MPPP claim.
- MPPP claims submitted on a different date of service have still have a 14-day timeframe, but a different start date.
- Payment and remittance expected to be like any other BIN/PCN combo the PBM administers.

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Medicare Prescription Payment Plan in the pharmacy workflow

- New Approved Message Codes (548-6F)
  - 056: Beneficiary likely to benefit from Medicare Prescription Payment Plan
  - 057: Beneficiary participating in Medicare Prescription Payment Plan
  - 058: Beneficiary no longer participating/has opted not to participate in Medicare Prescription Payment Plan
- New Reject Codes (511-FB)
  - DO1: Beneficiary is not a participant in this Medicare Prescription Payment Plan.
  - DO2: Matching Medicare Part D claim not found to allow processing for Medicare Prescription Payment Plan.
  - DO3: This claim is not eligible for Medicare Prescription Payment Plan.

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Medicare Prescription Payment Plan for long-term care pharmacy

- Pharmacies must provide a paper copy of the Likely to Benefit notice, but may do so in the usual billing cycle.
- May require additional education to LTC facility billing staff as well as LTC pharmacy billing staff.
- Information about MPPP is a good topic to present at an assisted living facility family night or similar gathering this fall.
- Prescriptions sold prior to opting in do not need to be submitted to the MPPP processor.
- Opt-in must be same person (patient or guarantor) that enrolls in the Part D Plan. Pharmacy and facility staff cannot opt in

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Medicare Prescription Payment Plan Audit risk

- Write a policy that the Likely to Benefit notice is given anytime a claim has Approved Message Code 056. Write the procedure for alerting staff to the situation and the steps staff take to ensure compliance. CMS requires Part D Plans to ensure that pharmacies provide the notice.
- Submit all eligible copays to the patient's MPPP processor.
- If a prescription isn't picked up, both the MPPP claim and the Part D claim need to be reversed.

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Medicare Part D 2026…
BIGGER changes coming

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Starting in 2026: Medicare Drug Price Negotiation

Secretary of HHS will negotiate pricing for:

- 2026: 10 drugs based on Part D spending
- 2027: 15 more drugs based on Part D spending
- 2028: 15 drugs more based on combined Part D and Part B spending
- 2029 and beyond: 20 more drugs based on combined Part D and Part B spending

Maximum fair prices (MFPs) were publicly released in August 2024

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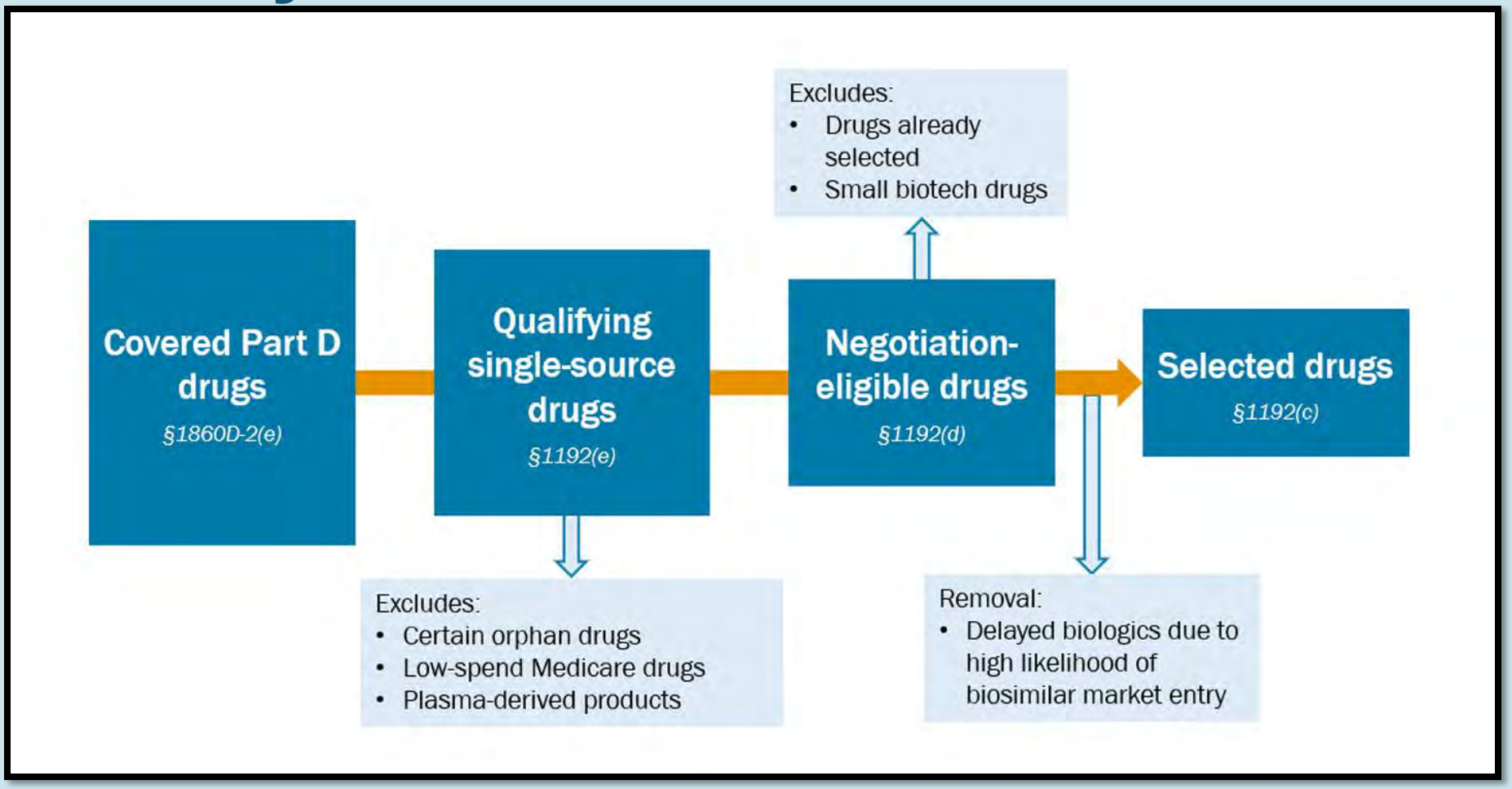
Figure 1: Diagram of Process for Selecting Drugs for Negotiation for Initial Price Applicability Year 2027



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

First 10 Drugs to be Negotiated

Drug	Loss of Exclusivity and generic launch timing*	Available generics/number of filers
Eliquis (apixaban)	Earliest possible: **4/1/2028** (70%)	20+ filers expected to share exclusivity
Enbrel (etanercept)	**4/24/2029**	3 potential biosimilars
Farxiga (dapagliflozin)	**Already occurred**	Authorized generic launched; 10+ additional entrants expected in April 2026
Fiasp/Novolog (insulin aspart)	**Already occurred**	Nordisk has an unbranded biologic available. Gan & Lee/Sandoz and Amphastar have biosimilars pending approval with FDA. GeneSys/Civica has a biosimilar in development.
Entresto (sacubitril/valsartan)	Earliest possible: **4Q 2024** (40%) Most likely: **2025** (70%)	17 total filers; 1 may launch "at risk" in 2024 with additional launches possible in 2025
Imbruvica (ibrutinib)	**3/30/2032** (70%)	3 filers total; 2 will potentially launch first without exclusivity
Januvia (sitagliptin)	**5/2026** (80%)	2 filers appear to be eligible for shared 180-day exclusivity, with 10+ additional filers likely to launch after the exclusivity period
Jardiance (empagliflozin)	Earliest possible: **2/2/2029** (40%) Most likely: **10/2034** (60%)	10+ filers appear to be eligible for shared 180-day exclusivity, with additional filers likely to launch after the exclusivity period
Stelara (ustekinumab)	**1/2025**	
Xarelto (rivaroxaban)	**3/1/2025** (70%) for 2.5 mg tablets; 2027 for other strengths	1 filer may have exclusivity for the 2.5 mg strength; no exclusivity is expected for other strengths

*LOE date and proprietary estimate of probability is based on IPD Analytics' patent analysis.

Table 9: Removal from the Selected Drug List Following Generic Drug or Biosimilar Approval and Marketing

Date on which CMS determines that a generic drug or biosimilar is approved and marketed	Result with respect to selected drug for the Negotiation Program
The date that the selected drug list for initial price applicability year 2027 is published through November 1, 2025 (the end of the Negotiation Period for the initial price applicability year 2027)	Selected drug remains a selected drug for initial price applicability year 2027, though MFP does not apply; selected drug ceases to be a selected drug on January 1, 2028.
November 2, 2025 through March 31, 2027	Selected drug remains a selected drug and MFP applies for initial price applicability year 2027; selected drug ceases to be a selected drug on January 1, 2028.
April 1, 2027 through March 31, 2028	Selected drug remains a selected drug and MFP applies for initial price applicability year 2027 and calendar year 2028; selected drug ceases to be a selected drug on January 1, 2029.

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

Projected Savings for People with Medicare Part D

Drug Name	Participating Drug Company	Commonly Treated Conditions	Agreed to Negotiated Price for 30-day Supply for CY 2026	List Price for 30-day Supply, CY 2023	Discount of Negotiated Price from 2023 List Price	Total Part D Gross Covered Prescription Drug Costs, CY 2023	Number of Medicare Part D Enrollees Who Used the Drug, CY 2023
Januvia	Merck Sharp Dohme	Diabetes	$113.00	$527.00	79%	$4,091,399,000	843,000
Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill	Novo Nordisk Inc	Diabetes	$119.00	$495.00	76%	$2,612,719,000	785,000
Farxiga	AstraZeneca AB	Diabetes; Heart failure; Chronic kidney disease	$178.50	$556.00	68%	$4,342,594,000	994,000
Enbrel	Immunex Corporation	Rheumatoid arthritis; Psoriasis; Psoriatic arthritis	$2,355.00	$7,106.00	67%	$2,951,778,000	48,000
Jardiance	Boehringer Ingelheim	Diabetes; Heart failure; Chronic kidney disease	$197.00	$573.00	66%	$8,840,947,000	1,883,000
Stelara	Janssen Biotech, Inc.	Psoriasis; Psoriatic arthritis; Crohn's disease; Ulcerative colitis	$4,695.00	$13,836.00	66%	$2,988,560,000	23,000
Xarelto	Janssen Pharms	Prevention and treatment of blood clots; Reduction of risk for patients with coronary or peripheral artery disease	$197.00	$517.00	62%	$6,309,766,000	1,324,000
Eliquis	Bristol Myers Squibb	Prevention and treatment of blood clots	$231.00	$521.00	56%	$18,275,108,000	3,928,000
Entresto	Novartis Pharms Corp	Heart failure	$295.00	$628.00	53%	$3,430,753,000	664,000
Imbruvica	Pharmacyclics LLC	Blood cancers	$9,319.00	$14,934.00	38%	$2,371,858,000	17,000

Note: Numbers other than prices are rounded to the nearest thousands. List prices are rounded to the nearest dollar and represent the Wholesale Acquisition Costs (WACs) for the selected drugs based on 30-day supply using CY 2022 prescription fills. Drug companies' participation in the Negotiation Program is voluntary; the figures above represent estimates based on continued drug company participation in the Medicare program.

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Source: https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf

After years of increases, a cascade of cuts to prescription drug prices is becoming The NEW NORMAL

Source: Senior Care Pharmacy Coalition

Why the WAC decreases?

As of January 1, 2024, the American Rescue Plan Act (ARPA) lifted the cap on the total amount of rebates that Medicaid could collect from manufacturers who raise drug prices substantially over time.

- **Decreasing WAC's allows mfg. to avoid increased Medicaid rebates.**
- Recent changes include price cuts for insulin and the discontinuation of Flovent, among others.

On the horizon… Spiriva HandiHaler, Atrovent, Januvia

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Maximum Fair Price (MFP) Effectuation

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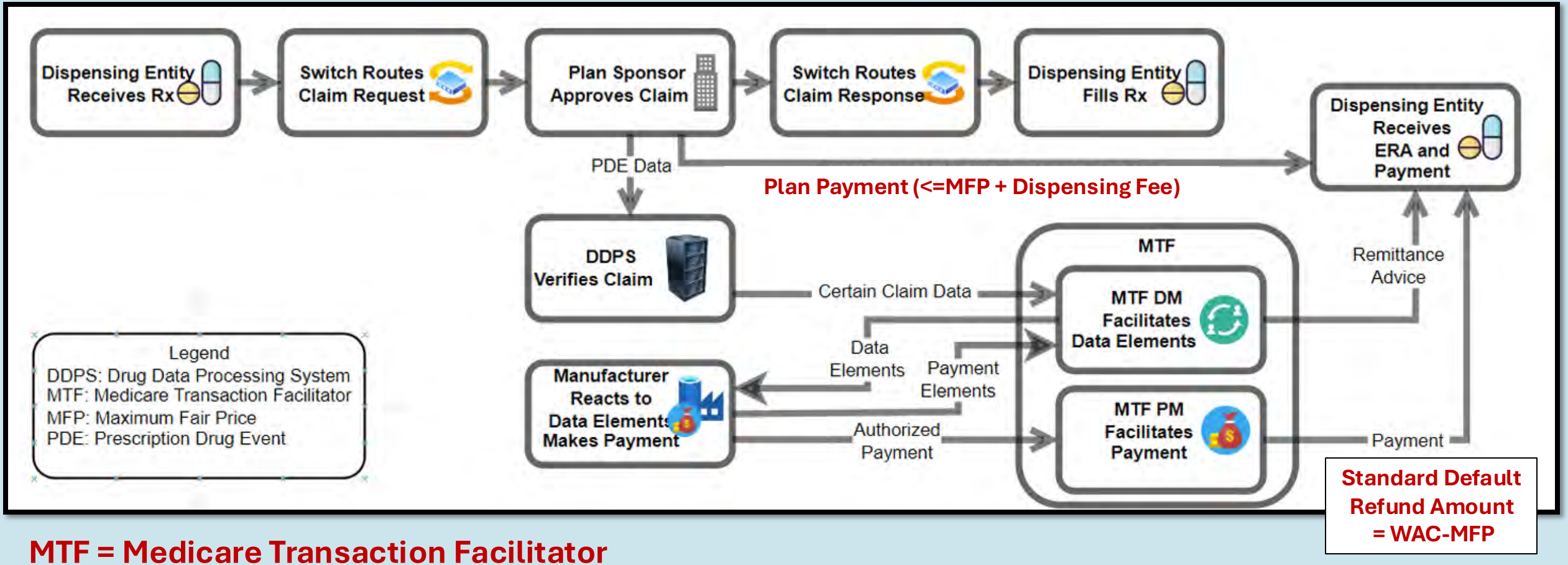
Figure 3: Diagram of MTF Payment Flow for Primary Manufacturers that Participate in the MTF PM



MTF = Medicare Transaction Facilitator

DM = Data Module

PM = Payment Module

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

Table 4: Example Manufacturer Claim-Level Payment Elements List for Primary Manufacturers Passing Payment through the MTF PM

Payment Elements	Purpose
Method for Determining MFP Refund Amount	Indicates the basis on which MFP refund amount was determined (refer to Table 5)
NPI of the Entity Receiving the MFP Refund	Documents the recipient of MFP refund
Quantity of Selected Drug	Documents the number of units of selected drug included in MFP refund paid
Amount of Payment to be Transmitted as the MFP Refund by the MTF PM	Indicates the amount the MTF PM should pay to the dispensing entity, prior to the application of any credits
MFP Refund Adjustment (Yes or No)	Indicates if the MFP refund payment was adjusted to a new MFP refund payment amount

* These elements are representative examples only, and CMS will provide the exact claim-level payment elements in forthcoming technical instructions as operations develop.

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

NCPA Asks for IRA/MFP Implementation

Note: CMS Final Guidance Released October 2

CMS Must Address Part D Plan Sponsor/PBM Payments to Pharmacies for MFP Drugs to Ensure Beneficiary Access to MFP Drugs

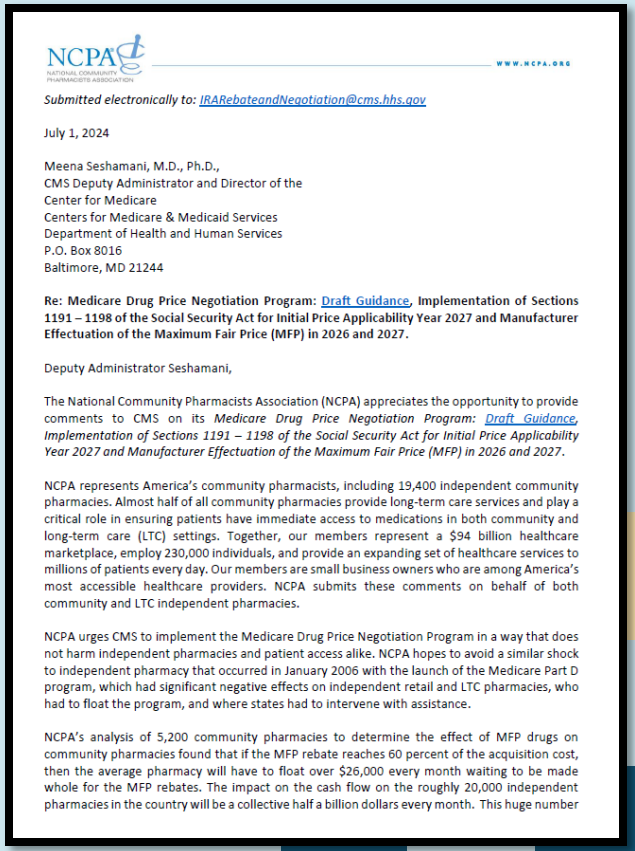
CMS did not adequately address

CMS must clarify that the **manufacturer should pay the pharmacy a rebate amount of the difference between Wholesale Acquisition Cost (WAC) and MFP**.

WAC minus MFP is the standard default refund amount , however, manufacturers can choose another amount

NCPA stresses that **pharmacies need to be paid timely**, within 14 days of adjudicating the claim.

The 14-day window does not begin until manufacturer receives MTF DM data. CMS states MFP refund payment will be in excess of 14 days from time of claim submission.



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WWW.NCPA.ORG

Submitted electronically to: IRARebateandNegotiation@cms.hhs.gov

July 1, 2024

Meena Seshamani, M.D., Ph.D.,
CMS Deputy Administrator and Director of the
Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.

Deputy Administrator Seshamani,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027.*

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $94 billion healthcare marketplace, employ 230,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

NCPA urges CMS to implement the Medicare Drug Price Negotiation Program in a way that does not harm independent pharmacies and patient access alike. NCPA hopes to avoid a similar shock to independent pharmacy that occurred in January 2006 with the launch of the Medicare Part D program, which had significant negative effects on independent retail and LTC pharmacies, who had to float the program, and where states had to intervene with assistance.

NCPA's analysis of 5,200 community pharmacies to determine the effect of MFP drugs on community pharmacies found that if the MFP rebate reaches 60 percent of the acquisition cost, then the average pharmacy will have to float over $26,000 every month waiting to be made whole for the MFP rebates. The impact on the cash flow on the roughly 20,000 independent pharmacies in the country will be a collective half a billion dollars every month. This huge number

NCPA Asks for IRA/MFP Implementation

Note: CMS Final Guidance Released October 2

CMS must mandate that the **Medicare Transaction Facilitator (MTF) generate an Electronic Remittance Advice (ERA), or 835, to the pharmacy** for purposes of reconciling manufacturer retrospective MFP refunds.

CMS will mandate ERA

CMS must ensure **that payment for MFP drugs be reasonable and relevant.**

"CMS is not establishing requirements for dispensing fees for selected drugs at this time but will monitor complaints and audits related to this issue. CMS encourages plan sponsors to work with pharmacies to ensure adequate and fair compensation for dispensing selected drugs."

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IRA MFP Concerns

NCPA's analysis of 5,200 community pharmacies to determine the effect of MFP drugs on community pharmacies found that **the average pharmacy will have to float over $27,000 every month waiting to be made whole for the MFP refund payments from the manufacturers.**

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NCPA's analysis of 5,200 community pharmacies to determine the effect of MFP drugs on community pharmacies found that the average pharmacy will have to float over $27,000 every month waiting to be made whole for the MFP refund payments from the manufacturers.

The **impact on the cash flow on the roughly 20,000 independent pharmacies in the country will be a collective half a billion dollars every month**. This huge number *is only for year one* of the MFP program and **will grow larger and larger as more drugs are added each year**, resulting in devastating, irreparable impact on pharmacies serving most vulnerable and at-risk patients, especially those serving long-term care facilities.

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Tiny olive branch

Dispensing Entity Self-Identification of Material Cashflow Concerns: In section 40.4.2.2, CMS added that during enrollment in the MTF DM dispensing entities will be asked to self-identify whether they are dispensing entities that anticipate having material cashflow concerns at the start of the initial price applicability year due to the reliance on retrospective MFP refunds within the 14-day prompt MFP payment window. This information will be provided to Primary Manufacturers to assist in the development of their MFP effectuation plans, as described in section 90.2.1 of this final guidance.

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Tiny olive branch

Inclusion of Mitigation Processes for Material Cashflow Concerns in MFP Effectuation Plans for 2026 and 2027: In section 90.2.1, CMS added that Primary Manufacturers must include a process for mitigating material cashflow concerns for dispensing entities in their MFP effectuation plans. For consideration in developing and implementing this mitigation process, CMS will make the list of the self-identified dispensing entities (described in more detail in section 40.4.2.2) available to Primary Manufacturers in the MTF DM prior to Primary Manufacturers' submission of their MFP effectuation plans for 2026 and 2027.

Examples of processes to mitigate material cashflow concerns for identified dispensing entities may include, but are not limited to, prospective purchasing agreements or accelerated MFP refund timelines.

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IRA MFP Concerns

Goal is to lower out of pocket costs for patients who use these drugs, however, PBM's ARE NOT REQUIRED to place these drugs on their lowest cost-sharing tiers.

Pharmacies will still be purchasing these drugs at the same prices they do today from their wholesalers.

CMS must require Part D plans and PBM's to pay pharmacies NO LESS than the maximum fair price PLUS a commensurate dispensing fee when providing these drugs to patients, and CMS SHOULD MANDATE THAT PBM'S CANNOT ASSESS DIR FEES ON THE MFP DRUGS.

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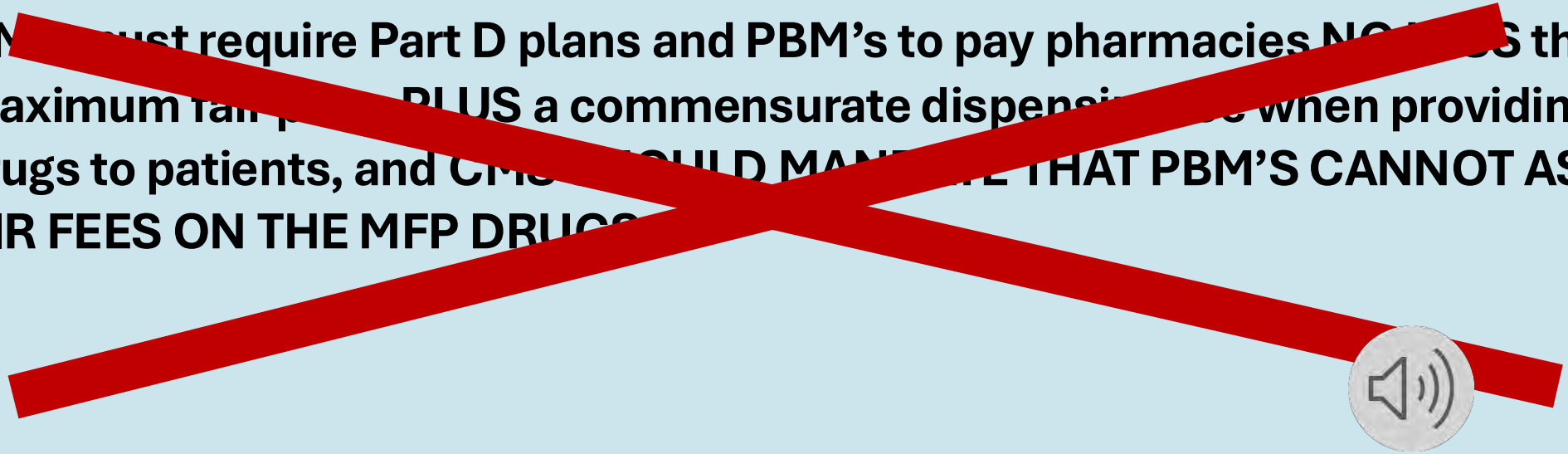

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Bottom line

NCPA: Biden's Drug Program Will Fail if Pharmacies Are Paid Too Little and Too Late

ALEXANDRIA, Va. (Oct. 3, 2024) – The National Community Pharmacists Association today warned that President Biden's plan to negotiate drug prices...

NEWS RELEASES | OCT 03, 2024

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NCPA: Biden's Drug Program Will Fail if Pharmacies Are Paid Too Little and Too Late

CMS' failure to require timely, sufficient pharmacy reimbursement will lead to closures not seen since the start of Part D and patients will suffer as a result

NCPA • October 3, 2024

ALEXANDRIA, Va. (Oct. 3, 2024) – The National Community Pharmacists Association today warned that President Biden's plan to negotiate drug prices in Medicare will fail and patient access to the first 10 negotiated drugs will be jeopardized beginning in 2026 because the Centers for Medicare & Medicaid Services neglected in its final guidance to prevent pharmacy benefit managers and manufacturers from paying pharmacies too little and too late.

In comments to CMS on the draft guidance, NCPA stressed the need for the agency to ensure that PBMs reimburse community and long-term care pharmacies fairly for maximum fair price (MFP) drugs — at a negotiated price that is no lower than the maximum fair price plus a commensurate professional dispensing fee. NCPA also emphasized that manufacturers must refund pharmacies within 14 days of adjudicating the claim. Otherwise, according to an NCPA analysis, the average pharmacy will have to float over $27,000 every month waiting to be made whole from the manufacturer refunds. Collectively among community and LTC pharmacies, the cash flow

NCPA IRA Concerns Intensified for LTC Pharmacies

- Increased volume of business in Medicare Part D
- Mandate to fill prescriptions for patients in LTC
- Same terms from wholesalers as retail pharmacies
- For Part A contracts with the facility, the facility must be billed at the higher price, not the new MFP → facility pays more for these drugs
- More at risk for LTC pharmacies

Patients ultimately suffer.

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Questions?

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