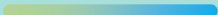


# Approaches and Considerations for Effectuating MFP



MDRP

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PRESENTED BY

Riparian // King & Spalding

# With You Today



**Jennifer Lospinosa**  
*President, Riparian*

Nearly 20 years of experience in government and commercial program operations. Her work centers on new solutions for pharmaceutical manufacturers navigating government programs and commercial discount strategies.

Before Riparian, Jennifer was a Managing Director at KPMG, leading projects in regulatory compliance, gross-to-net forecasting, and operational improvement. Before that, she spent over seven years at Novartis focused on government rebates, contracting, and financial analysis.

## INTRODUCTIONS



**Erin Rivas**  
*Associate Director, Riparian*

Over a decade of experience in commercial operations for pharmaceutical manufacturers and payers. Her recent work focuses on the maximum fair price under the Medicare Drug Price Negotiation Program: defining requirements, supporting system implementation, and building the policies and procedures that keep the program running.

Erin has supported manufacturers across all three negotiation cycles and continues to support live MFP operations for first-cycle manufacturers.



**Caitlyn Ozier**  
*Counsel, King & Spalding*

Counsels pharmaceutical, biotechnology, and medical device companies on regulatory, compliance, and enforcement issues affecting sales, marketing, and pricing.

Caitlyn advises clients on the laws that govern drug pricing decisions and has extensive experience with the Inflation Reduction Act's Medicare Drug Price Negotiation Program from drug selection through negotiation and maximum fair price effectuation.

# Agenda



- **MFP Program Fundamentals & Essential Requirements**
- **Implementation Strategy & Practical Approaches**
- **Deadlines & Documentation Requirements**
- **Looking Ahead**
- **Key Takeaways & Q&A**

# Medicare Drug Price Negotiation Program

- Enacted in 2022 as part of **Inflation Reduction Act**
- Enables Medicare to negotiate prices for certain high expenditure, single source drugs and biological products and establish a “**maximum fair price**” or MFP
- Several entities filed suit challenging the law

## Drug Eligibility

- Medicare Part D drugs
- Medicare Part B drugs (beginning IPAY 2028)

## Drug Selection

- High spend drugs
- Exclude drugs newer than 7/11 years

## “Voluntary” Negotiation

- Manufacturer of selected drug can decline to participate so long as they withdraw all FDA-approved drugs from Medicare/Medicaid
- Manufacturers must submit Negotiation Data Elements ICR

## MFP Duration

- Until generic or biosimilar actively marketed

## Renegotiation

- Selected drugs can be identified by CMS for renegotiation if certain factors exist

## Access Mandate

- Once an MFP is established, manufacturers must ensure MFP is made available

## 340B Non-Duplication

- Manufacturers are not required to provide access to both MFP and 340B ceiling price

## Penalties

- Noncompliance excise tax for refusing to participate or failing to reach MFP agreement with CMS
- CMPs for failing to make MFP available

# CMS Regulatory Authority

## IPAY 2026 – IPAY 2028

- *“The Secretary of Health and Human Services shall implement this section, including the amendments made by this section, for 2026, 2027, and 2028 by program instruction or other forms of program guidance.”*

## IPAY 2029 and Going Forward

- On June 16, 2026, CMS issued proposed rules to codify the Negotiation Program policies
- CMS expects to finalize rules in Fall 2026 for the IPAY 2029 negotiation cycle (that begins in early 2027)

# MFP Program Fundamentals & Essential Requirements

## What is Maximum Fair Price (MFP)?

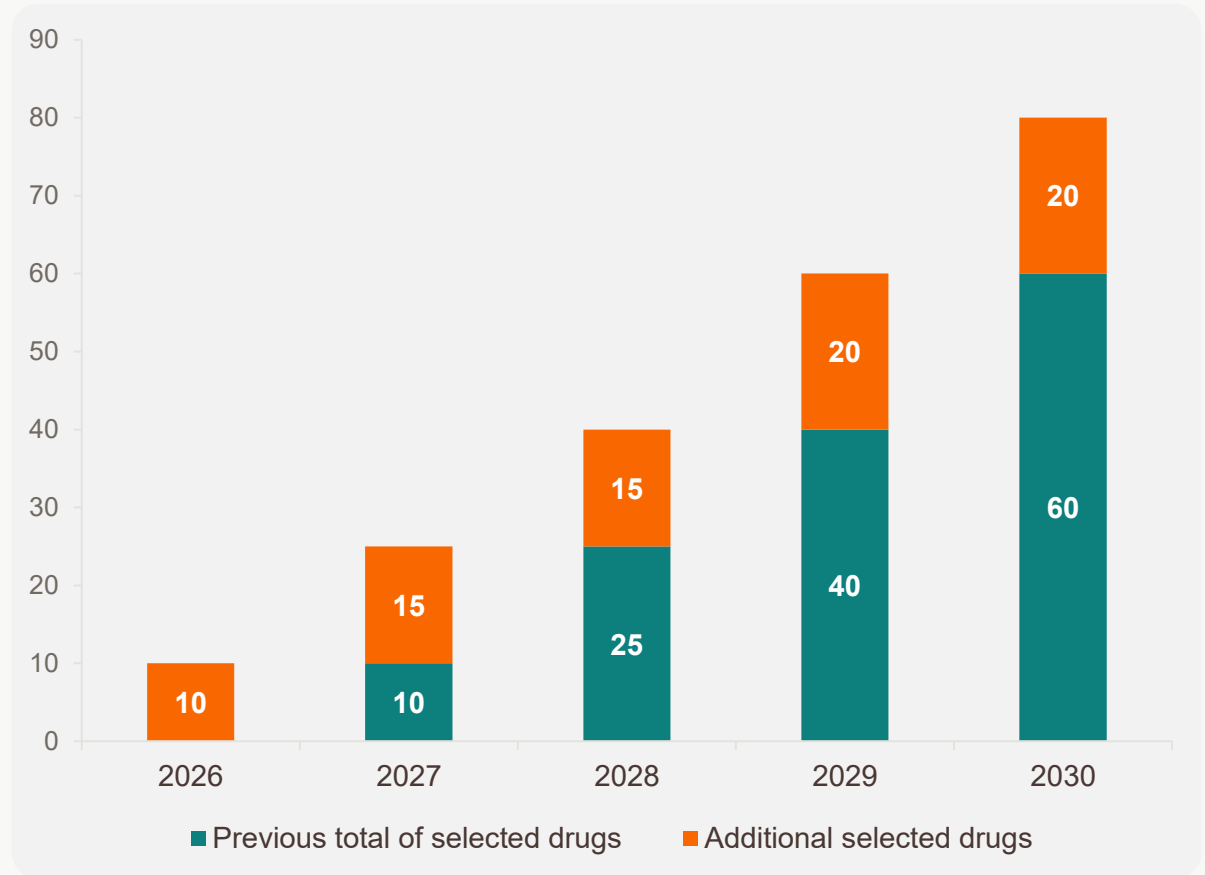
- CMS can negotiate a 'maximum fair price' for certain high-expenditure selected drugs sold without generic or biosimilar competition. The price manufacturers charge cannot exceed the statutory MFP ceiling.

## Access to MFP

- The Primary Manufacturer of a selected drug must make the MFP available to dispensing entities and providers that dispense or administer it to MFP-eligible individuals: Part D beneficiaries for 2026 and 2027, expanding to Part B beneficiaries beginning 2028.
- Access can be made:
  - Prospectively (the price paid at the point of acquisition), or
  - Retrospectively (a refund for the difference)

## Impact

- By 2030, up to **80 drugs may be subject to an MFP**.



# Manufacturer Requirements for MFP Effectuation

1

Provide access to the **MFP** at the **point-of-sale** to MFP-eligible individuals

2

Provide access to the **lower of the MFP or 340B ceiling price** on eligible units dispensed by 340B covered entities.

3

Refund the dispensers/ providers **within 14 days** of receiving claims data.

4

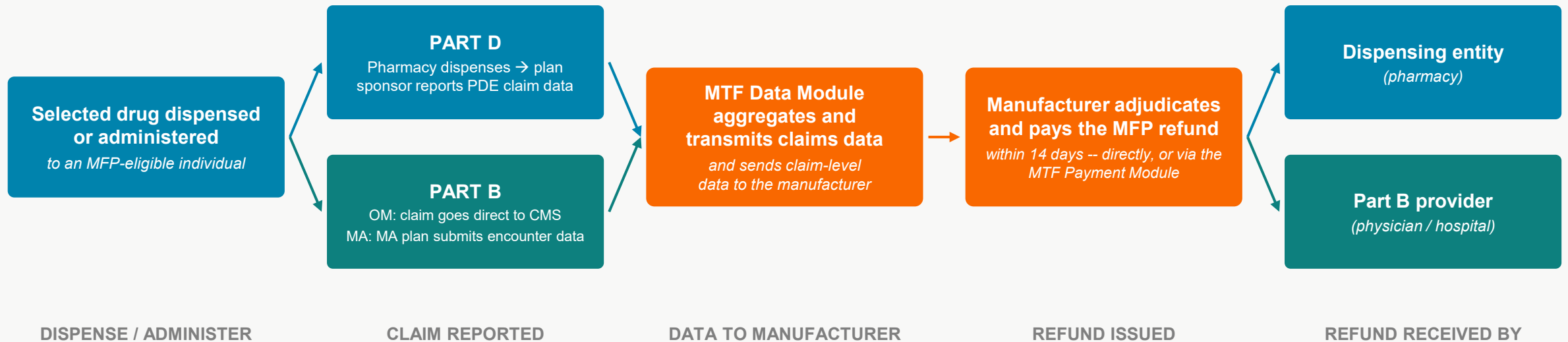
Identify **340B** and **MFP duplicate** discounts.

5

Mitigate **cash flow constraints** for certain dispensers/ providers.

# How MFP Flows Through the Supply Chain

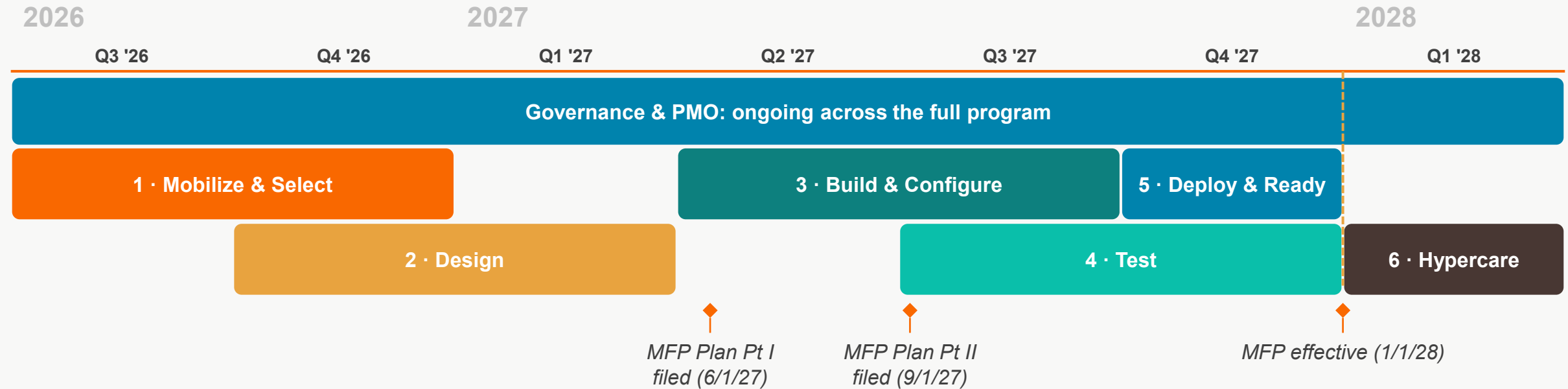
MFP-eligible individual does not pay more than the MFP



# How MFP Flows Through the Manufacturer

- 1 Claim intake** · *MTF Data Module / MFP solution*  
MFP claim-level data is transmitted to the MFP solution through the MTF DM.
- 2 Claim adjudication** · *MFP solution*  
MFP claim validated, 340B duplicates identified, and MFP refund is calculated (acquisition basis minus MFP, applied to units dispensed/ administered).
- 3 Claim response** · *MFP Solution / MTF Data Module*  
MFP solution transmits claim payment response file to the MTF DM
- 4 Claim payment** · *ERP / MTF Payment Module*  
Manufacturer authorizes payment facilitation through the MTF PM within 14-days of receiving claims data from MTF DM.
- 5 Claim reconciliation** · *ERP / finance systems*  
Adjudication, withdrawal, and payment records are reconciled to the general ledger.

# A Typical IPAY 2028 Implementation Timeline



- Early engagement buys more runway for vendor selection, governance setup, and data readiness.
- Sequence workshops around the decisions that unblock downstream vendor work.
- **Typical deliverables:** implementation plan, RACI, RAID log, requirements specification, future-state process flows, functional configuration specification, test strategy/scripts, traceability matrix, go/no-go package, hypercare plan.

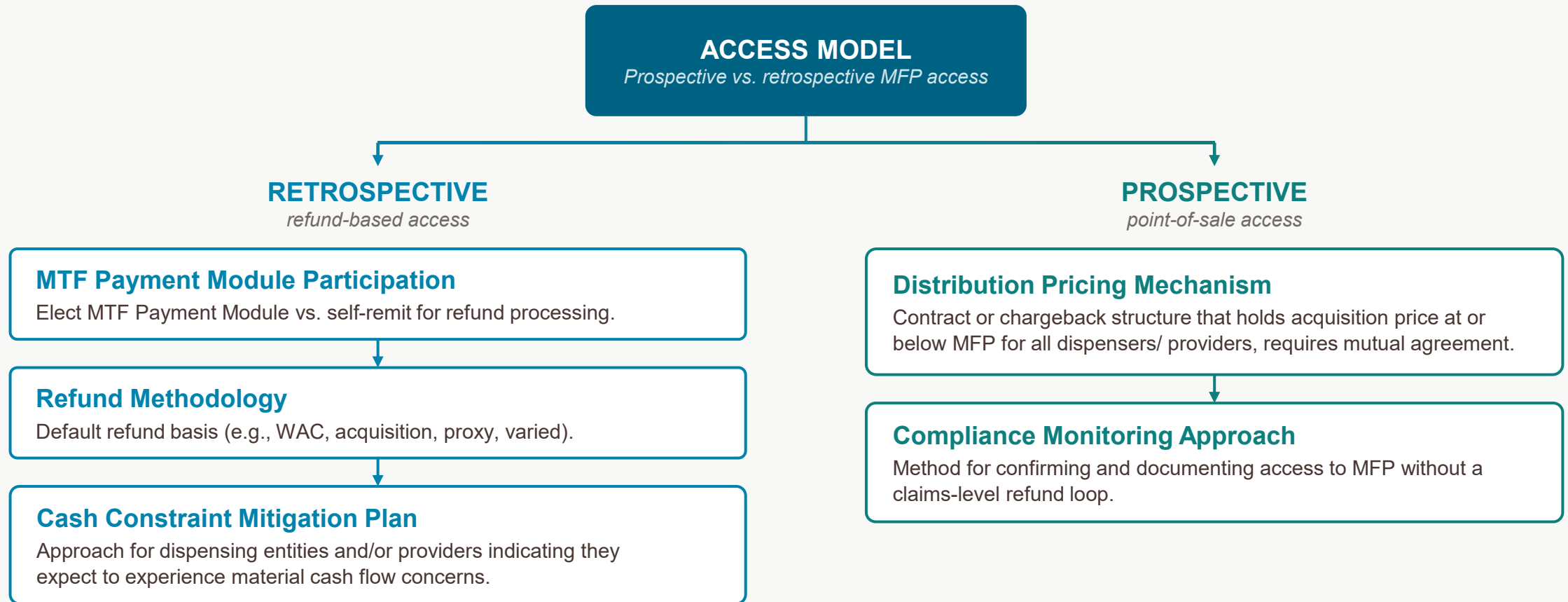
# Stakeholder RACI: Governance Across the Program

This governance structure holds across both pre- and post-implementation phases.

| Tier                        | Who                                                                        | Key Responsibilities                                                                                                                |
|-----------------------------|----------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| <b>Steering Committee</b>   | Sponsor-level executives                                                   | Final approval on major program decisions and escalations; sets strategic direction                                                 |
| <b>PMO</b>                  | Program / project management                                               | Owns the project plan and status reporting; makes project-level decisions; resolves issues and escalates on a standing cadence      |
| <b>Functional Core Team</b> | Cross-functional SMEs (Ops, Pricing, Finance, Contracting, IT, Compliance) | Defines requirements, validates solutions, and makes day-to-day operational decisions; communicates risks and roadblocks to the PMO |
| <b>Extended Team</b>        | Ad hoc SMEs (Public Affairs, Payer/Trade Relations, Market Access, GTN)    | Periodic engagement on key decisions, updates, milestones and risks                                                                 |

# Key Decisions Define Implementation Strategy

*Early effectuation decisions define the requirements for the MFP solution*



# MFP Effectuation Plan Overview

## Due June 1

- ☐ MTF PM participation and alternative payment methods if opting out
- ☐ Communication plan for dispensers/ providers
- ☐ Mitigation plan for cash constrained dispensers/ providers

**Shared with MTF DM participants and possibly other interested stakeholders upon request**

## Due September 1

- ☐ MFP effectuation processes
  - 340B deduplication approach
  - Refund methodology
  - Frequency of payment response files
  - Secondary Manufacturer effectuation
- ☐ Alternative purchasing arrangements
- ☐ Compliance acknowledgements

**Not Shared with MTF DM participants or other stakeholders**

# Deadlines and Documentation Requirements

Consider legal/compliance engagement on aspects of both drug negotiation and implementation

## IPAY 2028 Timeline for Drug Selection/Negotiation:

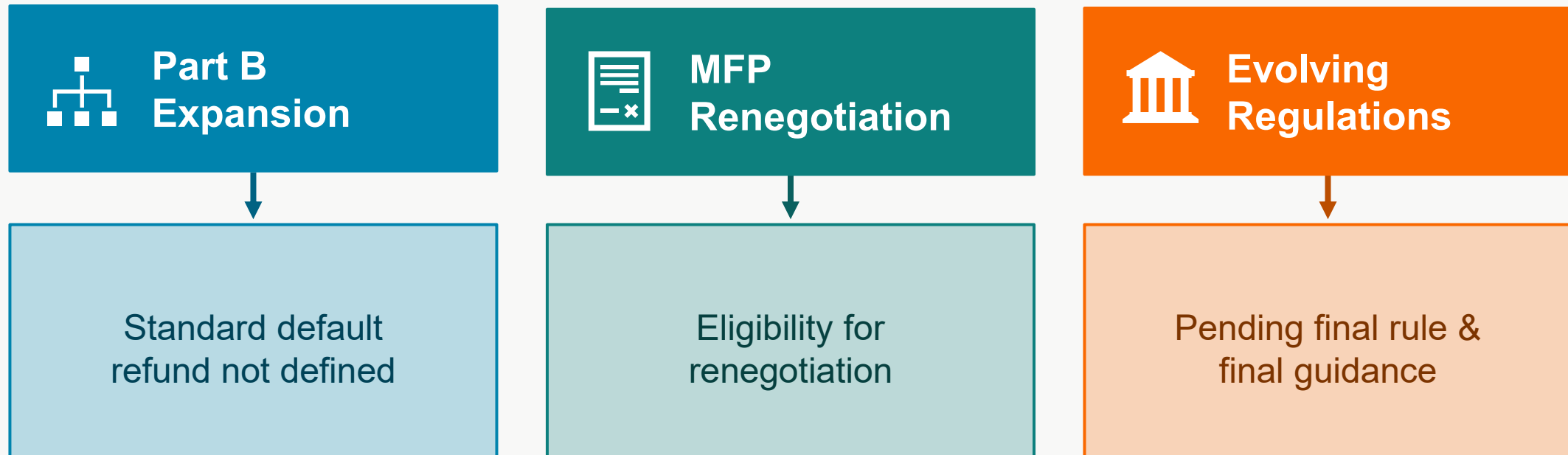
- **Feb 1:** CMS deadline to publish selected drug list
- **End of February:** Deadline for participating drug companies to sign agreements to participate in the Negotiation Program
- **March 1:** Deadline for participating drug companies to submit manufacturer-specific data to CMS for consideration in the negotiation of an MFP.
- **June 1 – October 31:** CMS and manufacturer negotiations
- **November 1:** Negotiation Period Ends
- **November 30:** CMS publishes agreed-upon MFPs

## Additional Requirements before MFP Implementation:

- **Submit MFP Effectuation Plan:** Details how a manufacturer intends to effectuate MFP
- **Sign MTF Contractual Agreements**
  - Mandatory: MTF DM Agreement
  - Voluntary: MTF PM Agreement

# Looking ahead

The Program will continue to evolve with high-stakes penalties for noncompliance



# Key Takeaways & Q&A



Early engagement and mobilization are critical to a compliant, execution-ready MFP program.

- **MFP effectuation is a complex, cross-functional effort involving multiple internal stakeholders and external vendors.**
- **Engage Legal early and establish clear governance, decision rights, and RACI to identify and address compliance and implementation risks before they become downstream issues.**
- **Mobilize the implementation team early to align stakeholders, vendors, dependencies, and timelines, and preserve sufficient runway for execution.**
- **With the regulatory and litigation landscape continuing to evolve, implementation plans should be flexible enough to adapt as requirements and interpretations change.**

**Regardless of where your company sits in the Program today,  
now is the time to begin preparing.**

# Q&A

# Thank You

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# Appendix: Key Terms & Glossary

## REFERENCE

**IRA.** Inflation Reduction Act: the law authorizing the Medicare Drug Price Negotiation Program.

**Selected Drug.** A high-expenditure drug without generic or biosimilar competition that CMS selects for negotiation.

**IPAY.** Initial Price Applicability Year: the first year a Selected Drug's Maximum Fair Price takes effect.

**MFP.** Maximum Fair Price: the price CMS negotiates with the Primary Manufacturer for a Selected Drug.

**Primary Manufacturer.** The manufacturer holding the NDA/BLA for a Selected Drug, responsible for negotiating and effectuating the MFP.

**Effectuation.** The operational process of making MFP-priced units available to MFP-eligible individuals, through prospective pricing or a retrospective refund.

**MTF (DM / PM).** Medicare Transaction Facilitator: CMS's system for exchanging claim data (Data Module) and facilitating payments (Payment Module, optional).

**340B Nonduplication.** The requirement to provide the lower of MFP or the 340B ceiling price on dually-eligible units, without applying both discounts to the same unit.

**SDRA.** Standard Default Refund Amount: a common refund methodology (generally WAC minus MFP, applied to units dispensed) used when claim-level effectuation isn't feasible.

**Effectuation Plan.** The filing a Primary Manufacturer submits to CMS, in parts, describing its approach to making the MFP available ahead of the IPAY go-live date.

**CMP.** Civil Monetary Penalty: the penalty CMS may assess for noncompliance with a negotiation agreement or MFP-access obligations.