**VIA ELECTRONIC DELIVERY**
irarebateandnegotiation@cms.hhs.gov

May 26, 2026

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

**RE: Designing Part B MFP Effectuation to Preserve Access for Patients with Rare Cancers**

Dear Administrator Oz,

The Protecting Innovation in Rare Cancers (PIRC) coalition has engaged with the Centers for Medicare & Medicaid Services (CMS) throughout its Medicare Drug Price Negotiation Program (MDPNP) implementation activities. In commenting to the Draft Guidance for IPAY 2028, we expressed our concerns that mechanisms for effectuating the negotiated maximum fair price (MFP) for Part B drugs could have unintended consequences for providers and patients.

PIRC is a collaborative, multi-stakeholder, patient advocacy coalition focused on improving access to and affordability of existing treatments while preserving incentives to advance future innovations in rare cancers. The coalition seeks to fulfill an important role in exchanging information, identifying, and resolving barriers to access and innovation, and educating both our rare cancer communities and policymakers on the Inflation Reduction Act (IRA) and its impact on rare cancer patients.

The undersigned PIRC participants would appreciate the opportunity to meet with CMS to ensure that the concerns and needs of Medicare beneficiaries, particularly those with rare

cancers, are fully considered and potential access constraints are proactively mitigated within the Part B drug MFP effectuation process. We have outlined our concerns and recommendations for CMS' consideration below and look forward to a collaborative discussion with CMS leadership and staff.

## Executive Summary

The Inflation Reduction Act requires manufacturers of selected drugs to provide access to the negotiated Maximum Fair Price (MFP) for eligible beneficiaries. While the statute establishes this obligation, it leaves CMS with discretion in determining how MFP will be effectuated within Medicare Part B's buy-and-bill system. For patients with rare cancers, that implementation decision will directly affect whether providers, including community oncology practices, rural hospitals, and specialized infusion centers can continue to deliver timely access to high-cost physician-administered therapies.

The negotiation process established under the Inflation Reduction Act is necessarily conducted between the federal government and manufacturers. However, the operational and access consequences of those negotiated prices are borne primarily by providers and patients—stakeholders who are not participants in the negotiation itself. This creates a structural disconnect between price-setting and care delivery. **While providers retain some degree of operational discretion in how they respond to these pressures—including decisions regarding stocking, site of care, and service offerings—patients ultimately bear the consequences of those decisions in the form of delayed, displaced, or foregone care.** As a result, the responsibility for ensuring that negotiated prices translate into real-world patient access—rather than unintended access barriers—rests with CMS' implementation of Part B effectuation.

Part B drug administration services operate on narrow margins and require significant working capital. If effectuation requires providers to finance negotiated discounts, manage inventory segmentation, undertake additional administrative processes, or absorb extended settlement delays, the likely result is reduced stocking, consolidation, Medicare Advantage network narrowing, and service-line contraction. For rare cancer patients, these operational shifts translate into delayed treatment, longer travel distances, or loss of local access.

To preserve access, CMS should prioritize evaluating the feasibility of a **CMS-routed or MAC-mediated settlement mechanism** under which manufacturers remit the negotiated

difference to Medicare and providers are reimbursed in a manner that leaves them financially whole at the point of administration. This approach directly addresses the central access risk identified by oncology stakeholders: provider financing of negotiated discounts.

If CMS determines that such a routed settlement mechanism is not feasible within current authority, it should adopt a **prospective-preferred framework**, permitting MFP access through standard distribution channels without requiring physical inventory segregation, supported by a **strict, time-limited reconciliation backstop** to protect providers from prolonged financing exposure.

Across any model CMS adopts, it should:

- Preserve beneficiary access at the point of care;
- Minimize provider financing burden and additional paperwork requirements;
- Establish clear duplicate discount protections, including at the intersection with 340B;
- Align Medicare Advantage implementation with fee-for-service timing standards;
- Continue publishing ASP for MFP-selected drugs to prevent destabilizing spillover into commercial markets; and
- Ensure manufacturers operate under a clearly defined, **bounded discount obligation**, supported by a streamlined, CMS-coordinated **duplicate discount prevention framework**, so that excess or unintended discounts arising from distributor behavior or data mismatches beyond a manufacturer's control do not destabilize the program.

The goal of Part B MFP effectuation is not simply to deliver negotiated savings. It is to deliver those savings without increasing costs elsewhere within the Medicare program or migrating discount mechanics into patient access barriers.

Importantly, these risks are not theoretical; they are consistent with observed provider behavior under reimbursement pressure and increasing administrative burden[1]. Recent analyses reinforce the magnitude of this risk. Independent modeling estimates that the shift from ASP-based reimbursement to MFP-based reimbursement will reduce provider

[1] Avalere Health, *Provider Perspectives on Medicare Drug Price Negotiation* (Sept. 2025); Association for Value-Based Cancer Care (AVBCC), *Issues and Challenges with the Effectuation of Maximum Fair Prices for Medicare Part B Drugs* (Oct. 2025).

reimbursement by approximately **$56 billion over ten years**[2], with oncology practices disproportionately affected. In parallel, survey data indicate that providers anticipate reducing stocking of high-cost therapies and altering care delivery patterns in response to reimbursement compression and administrative burden[3]. These findings underscore that effectuation design is not an operational detail—it is a primary determinant of whether patients can access Part B therapies in practice.

Similarly, early operational experience under Part D MFP implementation further underscores how reconciliation timing and administrative complexity can translate into real-world access friction.

## Background

Across all effectuation approaches under consideration, a consistent structural problem emerges: the negotiated discount is financed either by providers through cash-flow exposure or by operational complexity that functions as an indirect financial burden. While individual models differ in mechanics, they converge on the same outcome—providers are left with either reduced reimbursement, increased administrative burden, or both. For providers operating under narrow margins in Part B, particularly in oncology and rare disease settings, this is not a manageable tradeoff. It is a destabilizing one.

Early implementation experience under Part D further reinforces these concerns. As MFP policies transition from framework to operational reality, stakeholders have begun to identify friction points related to reconciliation timing, administrative complexity, and variability in dispensing workflows. In particular, models in which product is dispensed at one price and reconciled later introduce operational and financial considerations for dispensing entities, including community-based oncology settings that rely on stable reimbursement structures to support care coordination, patient education, and adherence support. From a patient perspective, these dynamics manifest as delays in therapy initiation, variability in access across sites of care, or disruptions in continuity of treatment. While Part D and Part B differ structurally, these early experiences underscore the importance of minimizing additional operational friction in Part B effectuation design.

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[2] Milliman, *Impact of the Inflation Reduction Act on Part B Provider Payment and Patient Access to Care* (May 2025).

[3] Avalere Health, *Provider Perspectives on Medicare Drug Price Negotiation: Implications for Part B Beneficiary Access, Practice Operations, and Reimbursement* (Sept. 2025).

Accordingly, the central policy question is not which model is least burdensome, but whether any model, as currently conceived, can avoid shifting financial or operational burden onto providers in a way that ultimately affects patient access. For patients with rare cancers—who often rely on timely access to high-cost, physician-administered therapies delivered in specialized community or academic settings—the operational design of effectuation will directly shape access to care.

Under current law, drugs administered in physician offices and hospital outpatient departments are reimbursed based on Average Sales Price (ASP) plus a statutory add-on, effectively reduced by sequestration to approximately 104.3 percent of ASP. Providers purchase these drugs in advance and are reimbursed retrospectively, meaning that margins are narrow and working capital requirements significant. Large reductions in reimbursement levels or delays in settlement therefore have real implications for smaller practices and safety-net providers.

Community oncology practices, rural hospitals, independent infusion centers, and other Part B buy-and-bill sites frequently operate on thin financial margins and limited working capital[4]. Trends in consolidation, partly driven by pricing dynamics such as the 340B Drug Pricing Program, illustrate how economic pressures influence the delivery landscape. Over the past decade, participation in 340B has expanded substantially, and many hospitals have acquired community oncology practices or expanded outpatient facilities during periods of reimbursement tightening. These trends demonstrate how relatively small changes in margin structure can meaningfully reshape where and how patients receive care.[5]

However, the relationship between reimbursement pressure and delivery structure is not one-directional. While margin compression in office-based settings may accelerate consolidation toward hospital systems, many 340B-covered entities themselves rely in part on drug margin to support oncology infusion capacity, rural service lines, uncompensated care, and specialty staffing. If Part B MFP effectuation compresses spreads between acquisition cost and reimbursement, introduces refund uncertainty, or alters settlement timing in a way that disrupts cash flow, certain safety-net hospitals could also experience financial strain.

[4] AVBCC, *Issues and Challenges with the Effectuation of Maximum Fair Prices for Medicare Part B Drugs* (Oct. 2025).
[5] Avalere Health, *Estimating the Spillover Impact of IRA Part B Negotiation* (Jan. 2025).

The interaction between MFP and 340B mechanics warrants careful attention. If Medicare reimbursement reflects MFP while 340B ceiling price calculations remain unchanged—or if duplicate discount protections create operational ambiguity—covered entities could experience margin compression. At the same time, manufacturers must avoid impermissible duplicate discounts, adding compliance complexity. Clear operational rules are therefore essential to prevent unintended destabilization across both safety-net providers and manufacturers.

Put simply, the Part B drug system has a great deal of variability across providers, including on acquisition price, and for some providers it functions on narrow and carefully balanced spreads. If reimbursement or settlement timing become unpredictable, the financial strain does not disappear. It shifts. That strain may push independent practices toward consolidation, reduce service capacity at safety-net hospitals, or discourage stocking of high-cost rare cancer therapies. In each case, the economic pressure ultimately manifests as reduced patient access.

Rural hospitals face particularly acute vulnerability. When rural facilities close or eliminate oncology infusion services, patients are often required to travel long distances for care. For rare cancer patients, loss of a local infusion site is not a marginal inconvenience—it can represent the difference between timely treatment and delayed or foregone care.

At the same time, manufacturers and supply-chain partners must have predictable, auditable mechanisms that prevent excess or duplicative discounts while ensuring compliance with statutory requirements. If effectuation design exposes manufacturers to unbounded refund liability or operational ambiguity, countervailing distribution restrictions or administrative controls may emerge, again affecting patient access. Distributors and specialty wholesalers similarly require mechanisms that can be operationalized without inventory fragmentation or reimbursement misalignment that disrupts timely drug availability. Moreover, Medicare Advantage plans, which control network design and claim processing, are sensitive to reconciliation timing; delays or ambiguity in effectuation could encourage network narrowing or administrative controls that impact patients with rare disease or cancer.

Getting Part B MFP effectuation right is not solely a question of administrative mechanics—it is a patient access imperative. A sustainable approach must recognize the interconnected economic and operational pressures across providers, manufacturers, distributors, and Medicare Advantage plans. By proactively identifying where implementation friction could destabilize care delivery, CMS can design effectuation

policies that deliver negotiated savings while preserving access for patients who depend on Part B therapies, including those facing rare cancers.

## Statutory Framework and Implementation Boundaries

The Inflation Reduction Act requires manufacturers of selected drugs to ensure access to the MFP for eligible beneficiaries and directs CMS to establish mechanisms sufficient to ensure compliance and prevent duplicative discounts. The statute permits MFP to be provided either at the point of sale or through a refund mechanism, leaving CMS discretion regarding operational design.

That discretion must be guided by three core obligations:

**First, beneficiary access must be preserved at the point of care.** Patients should experience negotiated prices without delays, retroactive corrections, or site-of-care disruptions.

**Second, providers should not be required to function as the financing mechanism for negotiated discounts.** Particularly in oncology, rural, and safety-net settings, prolonged settlement timelines or unpredictable refund mechanics risk destabilizing fragile delivery infrastructure.

**Third, manufacturers must have predictable and auditable mechanisms that prevent excess or duplicative discounts while ensuring statutory compliance.** Effectuation models that expose manufacturers to unbounded or uncertain liability may prompt distribution restrictions or administrative controls that indirectly affect patient access.

## Structural Design Choice: Allocation of Financing Risk

All Part B effectuation models reduce to one of two structural approaches:

- **Prospective (front-end) effectuation**, where MFP is embedded in acquisition price prior to or at administration; or

- **Retrospective (back-end) reconciliation**, where the provider acquires drugs under standard terms and is later refunded the difference necessary to achieve MFP.

Across both approaches, the critical variable is who temporarily finances the negotiated discount. In a buy-and-bill system, that allocation of financing risk directly affects stocking decisions, consolidation dynamics, and patient access.

## Operational Failure Risk: Lessons from Competitive Acquisition

CMS previously attempted a Part B drug procurement model under the Competitive Acquisition Program (CAP). That program struggled due to:

- Matching specific purchases to individual claims,
- Inventory management complexity,
- Timing mismatches between ordering and administration,
- Provider reluctance to relinquish acquisition control.

Any Part B MFP effectuation model risks similar failure if it:

- Requires patient-specific ordering,
- Mandates separate physical inventories,
- Requires ex-ante eligibility confirmation before stocking,
- Creates uncertainty around drug availability at the point of care,

In oncology and rare disease settings, where therapy is often initiated quickly after clinical decision-making, delays caused by inventory or eligibility friction can translate directly into treatment postponement.

## Model Analysis

While multiple options have been proposed for effectuating the MFP, taken together these models do not present a meaningful policy choice between viable alternatives. Rather, they represent different pathways to the same underlying outcome: shifting financing burden and operational complexity onto providers within a system not designed to absorb either. Even where mitigation strategies are available, they reduce—but do not eliminate—these pressures. As a result, each model introduces access risk through provider adaptation to an evolving financial reality, including reduced stocking, site-of-care shifts, or administrative gating of therapy.

These risks are consistent with early operational experience under Part D MFP implementation, where reconciliation timing and administrative complexity have already begun to shape provider and dispensing behavior.

**Model 1: Prospective MFP Acquisition via Standard Distribution Channels (Chargeback-Style or Contract Pricing)**

Under this model, providers acquire drugs at or below the MFP up front through existing purchasing channels (e.g., wholesaler distribution under an MFP-based contract price, potentially supported by manufacturer chargebacks behind the scenes). In principle, the patient sees the negotiated price benefit immediately, refunds are minimized, and providers avoid financing discounts after administration.

The primary friction point is operational feasibility in a buy-and-bill world. If prospective access is implemented in a way that effectively requires providers to order on a patient-specific basis, to segregate inventory into "MFP eligible" and "non-MFP eligible" stock, or to confirm eligibility prior to stocking, then therapy initiation becomes vulnerable to delays and logistical failures. This is particularly concerning for rare cancers, where clinical urgency and scheduling constraints (e.g., infusion chair availability) mean delays can be clinically meaningful, and where many treatments are sourced through specialty distribution with limited surplus inventory maintained.

**Mitigation Approaches:** Even if CMS were to adopt measures such as virtual inventory accounting, post-administration eligibility verification, and fallback reconciliation pathways, these approaches would reduce—but not eliminate—operational friction.

**Residual Friction:** Even with these mitigations, providers must manage eligibility uncertainty, reconcile acquisition pathways, and potentially absorb acquisition price variability where MFP-aligned pricing is not consistently available through distribution channels. These requirements introduce workflow complexity and financial unpredictability that are not present in today's buy-and-bill system.

**Patient Impact:** In practice, this friction may manifest as delayed treatment initiation, reduced willingness to stock high-cost therapies, or preferential use of alternative treatments that are operationally simpler to administer—particularly in community oncology and rural settings.

**Model 2: Retrospective Refund to Providers Using a Transaction Facilitator–Style Architecture**

Under a retrospective refund model, providers purchase under ordinary terms and are later reimbursed by manufacturers for the difference required to ensure MFP access for MFP-eligible administrations. CMS has suggested that the Medicare Transaction Facilitator (or a similar infrastructure) could support data verification and payment processes. This model is attractive from a compliance standpoint because it can standardize verification and settlement and provide a clear audit trail. Unfortunately, it may be less provider-friendly and could increase access barriers.

The friction point within this model is the period between acquisition/administration and settlement. For high-cost infused therapies common in oncology and rare disease, providers may carry exceptionally large receivables. If refunds are delayed, disputed, or tied to encounter-data timing in Medicare Advantage, providers can experience meaningful cash-flow stress. The predictable downstream effect is reduced willingness to stock high-cost therapies for Medicare beneficiaries, increased patient reliance on larger systems, and acceleration of site-of-care shifts—each of which is an access risk for rare cancer patients that could erode savings to Medicare.

**Mitigation Approaches:** Enforceable settlement timelines, standardized default refund amounts, and streamlined remittance processes can improve predictability.

**Residual Friction:** Providers remain responsible for financing the gap between acquisition and reimbursement during the settlement period. For high-cost therapies, even short delays translate into significant working capital exposure. This is exacerbated in Medicare Advantage, where encounter data lags may extend reconciliation timelines beyond administratively meaningful limits.

**Patient Impact:** Providers facing sustained cash-flow exposure are likely to limit stocking of high-cost drugs, shift patients to hospital outpatient settings, or delay scheduling until financial certainty is achieved—each of which introduces predictable access barriers for patients requiring timely therapy.

**Model 3: Hybrid Patient-First Pricing with Rapid Provider True-Up**

This model is best understood as a patient protection overlay that can sit on top of either prospective or retrospective approaches. The defining feature is that beneficiaries

experience MFP-consistent cost-sharing at the point of care, while provider settlement occurs through either prospective acquisition or rapid true-up. The policy value is that patients do not become the reconciliation mechanism.

The friction point within this model is complexity and synchronization: aligning claims, eligibility verification, and settlement processes so that patient liability is correct without imposing operational burdens that trigger delays in therapy. This model is, however, often where stakeholder alignment becomes possible because it separates the patient experience (front-end) from the accounting mechanics (back-end).

**Mitigation Approaches:** Patient-facing protections (MFP-based cost sharing) combined with backend reconciliation can preserve beneficiary affordability.

**Residual Friction:** The model requires synchronization across claims processing, eligibility determination, and reconciliation workflows. This introduces operational complexity that may require new administrative infrastructure within provider practices.

**Patient Impact:** While patient cost-sharing may be protected, access is likely to be constrained if providers experience administrative burden that limits throughput, delays scheduling, or discourages participation in the program for certain therapies.

**Model 4: MAC-Mediated or CMS-Routed Settlement That Leaves Providers Whole (The "Pass-Through" Concept)**

Patient and provider groups in oncology frequently advocate a model in which manufacturers settle the negotiated discount **to CMS** (or through Medicare Administrative Contractors), and CMS then adjusts provider reimbursement through existing payment rails. Conceptually, this approach is attractive because it can leave the provider "whole" at the point of purchase/administration—minimizing the risk that providers must carry negotiated discounts as receivables—and it can avoid requiring inventory segregation or patient-specific ordering. In other words, it appears to preserve the buy-and-bill delivery system while still ensuring that negotiated savings accrue to Medicare.

This model's greatest strength is also the reason it must be analyzed carefully: it shifts settlement flows away from provider-manufacturer interactions and toward government payment rails. That can reduce provider friction, but it also raises material questions regarding statutory authority, implementation complexity, and how to ensure

manufacturers' obligations are satisfied while preventing duplicative discounts (including at the intersection with 340B).

**Mitigation Approaches:** Centralized settlement through CMS or MACs can remove provider financing burden and align reimbursement with existing payment systems.

**Residual Friction:** This model introduces questions regarding statutory authority, operational complexity, and coordination with existing programs (including 340B and Medicare Advantage). Absent clear authority and standardized processes, implementation uncertainty itself may create operational hesitation among stakeholders.

**Patient Impact:** If successfully implemented, this model offers the most direct pathway to preserving patient access by stabilizing provider participation. However, if pursued without clear authority or operational clarity, it risks delays or inconsistent application that could reintroduce access challenges.

## Medicare Advantage Considerations

Part B MFP effectuation in Medicare Advantage requires particular attention. MA plans control network design, prior authorization, and claims adjudication timing. If settlement timing in MA lags behind fee-for-service standards, providers in MA-heavy markets may face extended financing exposure, potentially leading to network narrowing or reduced stocking of rare cancer therapies. CMS should ensure MA settlement timing aligns with FFS standards and monitor network adequacy impacts for patient access to oncology providers and infusion sites for Part B oncology drugs.

Without alignment, Medicare Advantage implementation could become the primary driver of extended provider financing exposure within the Part B program.

## ASP Transparency Safeguard

CMS should continue publishing ASP for MFP-selected drugs. ASP serves as a critical transparency benchmark across Medicare and commercial markets, and manufacturers continue to report ASP data for selected drugs subject to an MFP. Discontinuing ASP publication risks accelerating destabilizing spillover into commercial reimbursement

structures, with downstream consequences for provider stability and patient access across both Medicare and commercial markets.[6]

## Recommendations

The most durable and access-protective approach is one in which providers are not required to finance negotiated discounts or absorb additional administrative burden as a condition of participation in the Part B program. This requires a mechanism—whether legislative or administrative—that ensures providers are reimbursed on an ASP-based construct (including the statutory add-on) while manufacturers satisfy negotiated obligations through a separate, centralized settlement pathway.

Absent such a structure, all effectuation approaches revert to some form of provider financing or operational burden, with predictable downstream effects on access to care. For purposes of Part B MFP effectuation, ensuring providers are "kept whole" means that providers are not required to:

- Finance the difference between acquisition cost and MFP;
- Absorb reductions in the statutory add-on tied to ASP; or
- Absorb material increases in operating costs due to new administrative processes

Existing legislative proposals reflect this same structural approach—maintaining ASP-based reimbursement for providers while reconciling negotiated discounts through manufacturer payments to the Medicare program—underscoring that a durable solution will likely require alignment between CMS implementation and Congressional action.[7]

We appreciate your consideration and look forward to a collaborative discussion to more fully communicate our concerns and to work with your team to ensure that Part B MFP effectuation delivers negotiated savings without undermining the delivery systems on which patients with rare cancers depend.

## Association of Cancer Care Centers (ACCC)

## Biomarker Collaborative

[6] Avalere Health, *Estimating the Spillover Impact of IRA Part B Negotiation* (Jan. 2025).
[7] AVBCC, *Issues and Challenges with the Effectuation of Maximum Fair Prices for Medicare Part B Drugs* (Oct. 2025) (discussing proposed legislative approaches to maintain ASP-based reimbursement with manufacturer-funded rebates).

**Cholangiocarcinoma Foundation**

**Chondrosarcoma Foundation**

**Cutaneous Lymphoma Foundation**

**Exon 20 Group**

**Histiocytosis Association**

**Hope for Stomach Cancer**

**ICAN, International Cancer Advocacy Network**

**MET Crusaders**

**NRG1 Energizers**

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**The National Pancreas Foundation**