COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

June 26, 2025

Chris Klomp
CMS Deputy Administrator and Director of the Centers for
Medicare & Medicaid Services
7500 Security Blvd.
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RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Submitted electronically to IRARebateandNegotiation@cms.hhs.gov

Dear Deputy Administrator Klomp,

Thank you for the opportunity to provide comments on the May 12, 2025, memorandum entitled "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028."

The Council for Affordable Health Coverage (CAHC) has long supported reduced drug costs, greater access to drug therapies, and fostering innovation to help treat and cure disease. CAHC (www.cahc.net) is a broad-based alliance with a singular focus: ensuring all Americans have access to affordable coverage. We are pro-patient, pro-competition, and pro-innovation. Our member organizations include employers, medical providers, patient groups, insurers, agents and brokers, technology companies, pharmaceutical manufacturers, and pharmacy benefit managers.

Briefly, CAHC is concerned that the current guidance perpetuates existing problems with the program while layering new challenges for Medicare beneficiaries, consumers generally, and advocates of an open and transparent government that is responsive to the people. We make the following recommendations in this letter:

1. Prevent the consolidation of markets that empower monopolies and raise prices for all consumers.
2. Follow the law and implement the IRA's drug selection process, and in applying the Orphan Drug Act provisions.
3. Immediately work to fix and operationalize the known problems with Medicare Transaction Facilitator to effectuate drug price controls at the point of sale.
4. Ensure the program is radically transparent and follows good government practices that hold bureaucrat decisions accountable while allowing broad understanding and input.

CAHC has previously commented on the first two years of the Medicare Drug Price Negotiation Program, which only impacted the Medicare Part D program. This year's draft guidance incorporates prescription drugs payable under Medicare Part B, of which CAHC has broad concerns.

Under the current program, health care providers who treat Medicare patients for cancer and other serious diseases will have their reimbursement cut for certain Part B physician-administered drugs. Part B providers are primarily reimbursed based on the product's average sales price (ASP) plus a 6% add-on payment, but under the IRA, the payment will be based on the MFP of the drug, which will be much less than the ASP.

Avalere estimates this could lead to more than a 50% reduction in add-on payments, translating into at least $25 billion in cuts to doctors, $12 billion of which would hit oncologists, specifically.[1] However, this cut to physician reimbursement will be even more dramatic if CMS chooses to include a selected drug's MFP in the calculation of its ASP. Many commercial payers use ASP as a metric for drug reimbursement, so the inclusion of MFP in the ASP calculation will also lower reimbursement for physician-administered drugs in the commercial market. To prevent government price controls from eroding physician reimbursement in the commercial market, CMS must explicitly exclude MFP from the calculation of ASP.

Overall, these massive cuts threaten the financial viability of many oncology practices, especially smaller or rural ones, which may no longer be able to afford cancer drugs priced above reimbursement rates. As a result, these practices may be forced to shut their doors or merge with hospital-based systems. When ASP was adopted in 2005, more than half of all Medicare oncology claims were from doctors in the community. Today, more than half are from more expensive hospitals. The IRA will accelerate this trend. And unfortunately for taxpayers, Medicare pays two to three times as much for hospital treatments than for doctors' services.

Large, metropolitan hospitals may absorb these reimbursement cuts, but smaller oncology practices in rural areas will suffer and may close or join the consolidation trend by joining a hospital. Access to proper care will become even more difficult for cancer patients.

Across markets, if the only choice for more patients is to receive care in a hospital-based setting, the IRA will raise costs for all consumers. For example, one study found hospital prices for the top 37 infused cancer drugs were 86.2% more per unit than in physician offices.[2] Research from AHIP showed hospitals charged 118% more than specialty pharmacies for the same drugs.[3] We encourage CMS to take a broader view of the impact of the IRA and the means it uses, and work with Congress to repeal the seriously flawed drug price provisions of the Inflation Reduction Act.

CMS should exclude MFP from the calculation of ASP to protect beneficiary access to Part B drugs, as the inclusion of the MFP in the calculation of ASP would further reduce ASP and extend provider reimbursement challenges to the commercial market.

In addition to our broad comment on the inclusion of Part B drugs in the negotiation program, we are submitting comments on the following sections of the draft guidance:

1. 30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2028
    a. 30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs
2. 40.4 Providing Access to the MFP in 2026, 2027, and 2028
3. 60.4 Negotiation Process
4. 60.5 Application of the MFP Across Dosage Forms and Strengths

[1] Avalere Health. (September 2024). https://advisory.avalerehealth.com/insights/commercial-spillover-impact-of-part-b-negotiations-on-physicians

[2] Employee Benefits Research Institute. (January 2020). https://www.ebri.org/content/cost-differences-for-oncology-medicines-based-on-site-of-treatment

[3] AHIP. (April 2023). https://www.ahip.org/resources/markups-for-drugs-cost-patients-thousands-of-dollars

30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2028

CAHC remains concerned that CMS's interpretation of what constitutes a qualifying single-source drug (QSSD) under Section 1192 of the Social Security Act continues to aggregate distinct and independently approved products that exceed the statute's scope and undermines incentives for innovation. As reiterated in the 2028 Draft Guidance, CMS identifies a qualifying single source drug based on the same active ingredient, aggregating all dosage forms, strengths, routes of administration, and formulations, even when they are approved under different New Drug Applications (NDAs) or biologics license applications (BLAs) and serve different clinical purposes." This interpretation is grounded in CMS's reading of Section 1192(d)(3)(B), which requires aggregation "across dosage forms and strengths of the drug, including new formulations." However, CMS's guidance misinterprets this clause to impermissibly group distinct products that have received separate FDA approvals and may differ substantially in their indications, safety profiles, delivery mechanisms, and target patient populations.

This aggregation practice introduces several harmful consequences. First, it allows CMS to subject newly approved drugs to price negotiation, even if the product in question has not been on the market for the required seven or eleven years, simply because it shares an active moiety with an older product. This undermines the law's explicit eligibility protections for newer therapies.

Second, it collapses clinically distinct products into a single pricing construct, devaluing research and development aimed at expanding indications, improving adherence, or meeting the needs of specialized populations, such as pediatric, elderly, or rare disease patients.

Third, this policy contradicts the regulatory distinction established by the FDA when it approves new NDAs or BLAs for a product with a shared molecule but unique properties or uses. By aggregating across distinct NDAs and BLAs, CMS not only misinterprets the statutory language but also effectively penalizes therapeutic innovation and deters continued investment in follow-on research that can significantly improve patient outcomes.

Additionally, in this section, CMS requested public feedback on aggregating certain fixed-dose combination products. CMS does not have the authority or expertise to assess whether any active ingredient is "biologically active" against the disease states for which the drug is indicated. It would be inconsistent with the FDA's definition of a fixed combination drug if CMS were to make these changes.

Recommendation: CMS should revise its approach to reflect the statutory requirement without exceeding its bounds. Specifically, CMS should treat each NDA or BLA as a distinct qualifying single-source drug unless there is clear and consistent regulatory evidence of interchangeability. Products that differ in route of administration, labeled indication, or target patient population should not be collapsed into a single pricing or selection construct simply because they share a molecular base. This distinction is essential to preserve incentives to innovate and to align the negotiation program with both the letter and the intent of the IRA. If left unchanged, CMS's current approach risks discouraging investment in high-value therapeutic advancements and diminishing access to meaningful new treatment options that improve beneficiary health outcomes. We urge CMS not to finalize any changes to the definition of a fixed combination drug.

30.1.1 Orphan Drug Exclusion from Qualifying Single Source Drugs

The narrow orphan drug exclusion was a vital piece of CAHCs comments on the Initial Price Applicability Year 2026, as the IRA made it clear that companies developing orphan drugs are now at increased risk of market failure – the opposite of what the Orphan Drug Act sought to address through tax, market exclusivity, and other incentives.

While CMS has since acknowledged these concerns and clarified that CMS does not have the authority to change the statutory requirement that prevents a drug with multiple designations from qualifying for the

orphan drug exclusion (ODE), more has to be done to protect and incentivize the development of these treatments. Additionally, since the first two rounds of negotiation, CMS has stopped seeking input on the necessary actions to improve orphan drug development under the current drug negotiation program, a blow to patients with rare diseases.

A recent analysis from the National Pharmaceutical Council found that the percentage of drugs with a first orphan designation that later received a second designation decreased by 48% following the passage of the IRA (12.1% to 6.3%).[4] The impacts of this policy failure are being felt in an already vulnerable population.

Recommendation: The House-passed version of the *One Big Beautiful Bill Act* [5] includes a provision to extend and clarify the exclusion of orphan drugs under Medicare's Drug Price Negotiation Program to allow product sponsors to have one or more orphan drug indications to qualify for the exemption. CMS should work with Congress to expand the orphan drug exemption and continue working with the relevant stakeholders to best understand how to address these issues.

40.4 Providing Access to the MFP in 2026, 2027, and 2028

CAHC remains concerned about CMS's continued reliance on a rigid 14-day payment window for manufacturer refunds to dispensing entities under the Medicare Drug Price Negotiation Program. The 2028 Draft Guidance reaffirms that "[CMS] expects that manufacturers make such payments within 14 days of the date the dispensing entity submitted the claim... whether directly or via a Medicare Transaction Facilitator (MTF)," and further clarifies that the MTF will serve only as a data conduit and "does not expect MTFs to adjudicate claims or handle funds directly."

This approach reflects an ongoing disconnect between CMS's policy timelines and the current capabilities of the pharmaceutical supply chain. The manufacturer-to-pharmacy refund pathway envisioned under this policy does not currently exist in any functional form. CMS acknowledges this reality in the guidance, noting the absence of direct relationships between manufacturers and dispensing entities, and offers two potential payment facilitation options: (1) transmittal of banking information only, and (2) pass-through of MFP refunds.

CAHC supports the pass-through option as the only viable mechanism for ensuring timely and accurate refunds while maintaining system integrity. Despite this policy recognition, CMS has not addressed the most critical challenge: the infrastructure necessary to reconcile and route daily claim-level payments between thousands of pharmacies and manufacturers does not exist, and certainly not at the scale and speed required to comply with a strict 14-day window.

In addition, while the MTF helps with the implementation of the MFP, it does not have the functionality to identify and prevent duplicate discounts, leaving the responsibility of deduplication on manufacturers and covered entities.

The operational complexity of this process, combined with the financial burden it places on manufacturers and smaller, community-based pharmacies, presents a significant threat to beneficiary access and system-wide compliance. Furthermore, the guidance offers no meaningful detail on the operational design or expected capabilities of the Medicare Transaction Facilitator (MTF). As a result, we are concerned MTF will not be operational by January 1, 2026. It is unclear how CMS intends to ensure consistency, dispute resolution, or standardized data exchange among entities with varying technical sophistication and claims systems. These unknowns risk destabilizing pharmacy operations and creating unpredictable delays in drug availability for Medicare beneficiaries.

[4] National Pharmaceutical Council. (May 2025). https://www.npcnow.org/resources/early-signals-ira-orphan-drugs
[5] https://www.congress.gov/bill/119th-congress/house-bill/1

Recommendation: CMS must take immediate steps to provide operational clarity and financial flexibility in the implementation of the MFP payment process.

1. First, the agency should direct the development of a robust facilitator infrastructure modeled on existing transaction platforms, particularly the Coverage Gap Discount Program, which already facilitates similar manufacturer refunds and can serve as a reliable foundation for MFP operations.
2. Second, we are recommending that CMS proactively address 340B duplicate discounts in Part B and D by requiring modifiers and establishing a 340B data clearinghouse. CMS should consider providing civil monetary payment relief for manufacturers operating in good faith when compliance is inhibited by factors outside of the manufacturer's control.
3. Third, CMS should provide a government-funded float or equivalent financial buffer to dispensing entities. This would allow pharmacies to dispense selected drugs at the point of sale without incurring unacceptable cash flow risks. Finally, CMS should formally consider a phased enforcement model that allows for a longer-than-14-day window during initial years and provide regular updates to stakeholders on the MTF's development, capabilities, and readiness benchmarks.
4. Finally, CMS asked for information on whether the Agency should adopt a standardized default refund amount with respect to Part B drugs. Considering the challenges around Part B MFP effectuation, including extended claims processing times, variance in provider acquisition costs, duplicate discounts and the Discarded Drug Refund Program, we recommend CMS adopt a standard default refund amount calculation based on ASP. The amount could be calculated as ASP minus MFP adjusted for add-on payments.

60.4 Negotiation Process

While CAHC appreciates that CMS has made some revisions to the negotiation program based on feedback from the first year of implementation, such as expanding comment periods and reiterating plans for public listening sessions, the negotiation process remains opaque.

In the 2028 Draft Guidance, CMS affirms that it "will continue to host public engagement events... and collect verbal input from patients and other stakeholders," but simultaneously clarifies that "these events are not intended to be decision-making forums." CMS also continues to state that it "will not disclose information related to the offers exchanged, the rationale for CMS's proposed MFP, or the final agreed-upon MFP, except as required by law."

Unfortunately, these disclosures confirm what stakeholders have experienced throughout the program's first year: the most critical elements of the negotiation process remain shielded from public scrutiny. CMS has yet to provide a clear explanation of how it uses stakeholder input; it has not released any analytical basis for how selected drugs were chosen or how maximum fair prices were determined; and it has provided no transparency into who is invited to participate in negotiation sessions or how those participants are selected.

Despite hosting a series of "patient-focused events," CMS has not explained how the feedback collected in those sessions was weighed or used to influence negotiation outcomes. Nor has CMS released a summary or report describing what perspectives were shared, what questions were raised, or whether any agency actions followed.

Additionally, CMS continues to impose sweeping restrictions on manufacturers' ability to speak publicly about their participation in the negotiation process. While Congress rightly directed CMS to protect proprietary information under Section 1198 of the IRA, nothing in the statute requires CMS to operate in near-total secrecy. Prohibiting manufacturers from sharing even basic facts about their role in the process, such as whether or how they responded to CMS's price proposals, chills public debate and erodes stakeholder trust. Transparency is not a threat to the program's integrity; it is a prerequisite for its legitimacy.

CAHC is further concerned that CMS has declined to release regulatory impact analyses or economic modeling conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), even though those analyses could help stakeholders and Congress better understand the expected downstream effects of the program. The agency's persistent refusal to share these materials raises serious concerns about accountability, especially given the program's scope and complexity.

Recommendation: CMS should embrace a more transparent and inclusive approach to stakeholder engagement that reflects best practices in public governance and honors the expectations of the Administrative Procedure Act, even if not formally required. Specifically, CMS should: publish summary justifications for drug selection and MFP determinations; release any non-confidential economic modeling or regulatory impact assessments from ASPE or other sources; lift unnecessary restrictions that prevent manufacturers from discussing their participation in the process; ensure transparency on how and why a particular therapeutic alternative was selected; and convert its public events from passive, listen-only formats to interactive forums that allow meaningful engagement, feedback, and follow-up. A law of this magnitude demands a public process that is as deliberative as it is fair. If CMS expects public trust in the negotiated prices it sets, it must offer the public insight into how and why those decisions are made.

Section 60.5 Application of the MFP Across Dosage Forms and Strengths

CAHC remains concerned about CMS's decision to apply a single Maximum Fair Price (MFP) across all formulations, dosage forms, strengths, and routes of administration for each selected drug, including for drugs that are approved under separate NDAs or BLAs, now for both Part B and Part D drugs. This blanket pricing approach is exacerbated by CMS's overly broad interpretation of QSSD and fails to reflect clinically meaningful differences across formulations that are critical to patient care. Drugs that have the same active ingredient or moiety but are approved or licensed under different NDAs or BLAs, have distinct formulations, oral versus injectable, extended-release versus immediate-release, pediatric versus adult, and often represent significant therapeutic advancements designed to improve safety, efficacy, adherence, or patient-specific outcomes.

Applying one MFP across such diverse products may result in reimbursement levels that do not reflect the actual cost or value of each formulation, further compounding the harm of CMS's interpretation of QSSD. This not only creates potential pricing mismatches at the point of sale but also sends a harmful signal to innovators that the development of tailored or more patient-centric formulations will not be valued or protected under the negotiation framework.

Recommendation: CMS should revise its definition of QSSD to recognize that drug and biological products approved under different applications are different QSSDs and should therefore receive different MFPs. In addition, where there is clear evidence that formulations approved under the same BLA or NDA differ in clinical use, indication, or patient population, CMS should consider creating differentiated MFPs. CMS could establish an exception process that incorporates FDA-approved labeling, drug delivery method, or therapeutic equivalency determinations to justify multiple MFPs for drugs that are approved under the same applications but are not functionally interchangeable. At a minimum, CMS should develop criteria for when separate pricing is appropriate and offer stakeholders the opportunity to submit supporting evidence as part of the negotiation process.

Conclusion

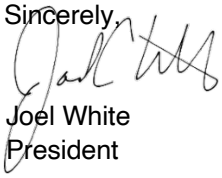
In an Executive Order from April 15, President Trump called for improved transparency of the Medicare Drug Price Negotiation program, efforts to minimize negative impacts of the MFP on pharmaceutical innovation, and expressed support for correcting the "pill penalty," which forces small molecule prescription drugs to be eligible for price controls 4 years before large molecule drugs.

Following the President's directives by preserving incentives for innovation, ensuring operational viability, and embracing transparency are not in conflict with cost control; they are essential to its success.

CAHC continues to support the administration's overarching goal of lowering prescription drug costs and improving affordability for Medicare beneficiaries. However, the policies outlined in the 2028 Draft Guidance raise serious concerns about operational feasibility, regulatory overreach, and unintended consequences for innovation, access, and patient care. As currently written, the guidance risks undermining the very progress it aims to achieve by introducing rigid systems without sufficient transparency, infrastructure, or respect for statutory limits. We urge CMS to revisit several of the assumptions embedded in this guidance and work collaboratively with stakeholders to implement the program in a way that is both sustainable and patient-centered.

We appreciate the opportunity to submit these comments and welcome further dialogue on how to ensure the Medicare Drug Price Negotiation Program is implemented in a manner that supports long-term value, equity, and trust. If you have questions about these comments, please do not hesitate to contact me.

Sincerely,



Joel White
President