Center on Health Policy at BROOKINGS

August 17, 2026

The Honorable Dr. Mehmet Oz, Administrator
The Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

Re: Medicare Program: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program [CMS-4215-P]

Dear Administrator Oz,

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule (CMS-4215-P, published June 16, 2026) "Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program." Most of the proposed rule **codifies existing initial price applicability year (IPAY) 2026–2028 guidance**, but CMS also proposes several substantive changes that would apply beginning with **IPAY 2029**. This group of experts writes to provide comments on several areas of the proposed rule.

General statement of support for the proposed rule

We write to express our general support for the proposed rule, CMS-4215-P, which would codify policies for the Medicare Drug Price Negotiation Program (MDPNP) under Sections 1191 through 1198 of the Social Security Act and make related updates to the Medicare Prescription Drug Benefit Program, consistent with Section 11001(b) of the Inflation Reduction Act of 2022 (IRA). Since the MDPNP's launch, CMS has implemented it through a series of guidance documents, each developed with input and feedback from stakeholders, including the use of public comment, and refined across three IPAYs. That approach gave the agency useful procedural flexibility to adjust policy as the program matured in the initial years of implementation.

As noted below, we generally support many policies in the proposed rule, and in our view several individual policies that codify the existing policies implemented through prior guidance are imperative to the success of the MDPNP and continuity of its operations. We also want to note specific support for individual policies in this proposal that clarify or adjust existing policies implemented through prior guidance:

- Slight modification under proposed § 429.105(c) to the tie-breaking methodology for drug selection from whole-dollar to cent-level precision, a small but sound improvement in the accuracy of the selection process.
- Reducing the published list of negotiation-eligible drugs ranked by spending from 50 to 30 each year, which continues to support transparency in the selection process while appropriately not overstating the predictive value of any single year's rankings.

The remainder of this letter will provide specific comments on six key topics and related proposals.

1. Modification to the fixed combination drug policy

Among the specific proposals in this proposed rule, CMS' proposed narrow modification to the fixed combination drug policy from its previous guidance document garners our support. Proposed § 429.125(b)(4)(i) addresses a specific program integrity gap that could otherwise arise between the general fixed combination drug policy and the statute's aggregation rules for new formulations. The proposed policy in this rulemaking applies only in a limited situation, when a manufacturer holds the approval for a drug and then markets a new formulation that combines that initial drug's active ingredient/moiety/antigen with an additional active ingredient/moiety/antigen, where the new ingredient/moiety/antigen enables the drug to be given through a different route of administration. Under the previously described fixed combination policy alone, this new combination would be treated as its own separate product. CMS' proposed modification clarifies that in these narrow circumstances, where the new and old formulations are held by the same manufacturer, CMS will instead aggregate the formulations that include an additional active ingredient/moiety/antigen enabling the new route of administration with all forms and strengths of the original active ingredient/moiety/antigen made by that manufacturer.

This modification addresses the potential program integrity risk involving a situation in which a manufacturer aims to reset the negotiation clock by making a slight adjustment to the drug or biologic, in this case by adding a new administration route to a product it already owns. Under the IRA, a drug's negotiation eligibility runs from its original approval or licensure date, and the statute instructs CMS to aggregate together any "new formulation" of an existing product. That is, a reformulation of an already-approved product is aggregated with the existing product, which stays tied to the original drug (or biologic) approval (or licensure) date. CMS' proposed approach directly implements the statute's existing distinction between new formulations of existing drugs/biologics and new drugs/biologics, and it does so with a scope narrow enough to avoid sweeping in genuinely novel combination drugs/biologics that would qualify as their own qualifying single-source drugs (QSSDs).

We support the modification to the fixed combination policy without reservation. Manufacturers have a clear economic incentive to structure combination products as new offerings whenever possible, if they believe that doing so can delay negotiation eligibility and preserve exclusivity-driven pricing for years or decades longer than the underlying active ingredient/moiety/antigen would otherwise support. CMS' proposal attenuates that incentive only in one respect that aligns strongly with the statutory aggregation requirement—where the same manufacturer already controls the original active ingredient/moiety/antigen and is layering on a new route of administration rather than bringing forward a distinct therapeutic advance. CMS' proposal is a meaningful, substantive check on a specific gaming strategy, not a blanket change in policy toward aggregation of fixed combination drugs/biologics generally; true combination therapies that pair active ingredients/moieties/antigens from different origins remain unaffected.

Given CMS' general reliance on an existing Food and Drug Administration (FDA) regulation (21 C.F.R. § 300.50) for CMS' definition of "fixed combination drugs," we think it is helpful to write and reiterate a point some of us have made in past comments to the agency.[1] This FDA regulation was first finalized in 1971[2] and serves a very different purpose than do the Negotiation Program's policies and procedures related to identifying QSSDs. The role of a combination drug designation by FDA is to determine the type and quantity of evidence required for product approval.[3] CMS, by contrast, is aiming to interpret the IRA's statutory instructions to identify a QSSD by aggregating data in a particular way. In our view, CMS is right to conclude that different types of combination drugs/biologics ought to be treated differently for purposes of QSSD aggregation. Some combination drugs/biologics should be considered as a "new formulation" of the original active ingredient/moiety/antigen, for aggregation purposes, while others should be considered as their own combination for QSSD purposes.

2. Orphan Drug rule

We express support for the proposed treatment of drugs that formerly qualified for the Orphan Drug Exclusion at § 429.125(c)(3)(i), which codifies an expansion to the IRA's original Orphan Drug Exclusion made by the 2025 Working Families Tax Cut legislation. Under current law, a drug that qualifies for the Orphan Drug Exclusion but later loses that status becomes subject to a 7-year (small-molecule) or 11-year (biologic) countdown before it can become negotiation-eligible. CMS proposes to start that countdown on the earlier of two triggering events: FDA approval of a non-orphan indication "irrespective of whether approval of such indication was or

[1] Richard G. Frank, Rachel Sachs, & Christen Linke Young, *Comments on Medicare Drug Price Negotiation Program*, The Brookings Institution (July 2, 2025), https://www.brookings.edu/articles/comments-on-medicare-drug-price-negotiation-program/.
[2] Food & Drug Admin., *Fixed-Combination Prescription Drugs for Humans*, 36 Fed. Reg. 20037 (Oct. 15, 1971).
[3] In Re Alcon Lab's Inc., 13 U.S.P.Q.2d 1115 (Com'r Pat. & Trademarks 1989) (quoting from a May 10, 1989, letter from Stuart Nightingale, M.D., Associate Commissioner for Health Affairs at FDA).

is withdrawn after its approval," or withdrawal of an orphan designation "if that withdrawal results in the drug or biological product no longer qualifying for the orphan drug exclusion."

Absent a clear rule on the timing and criteria, a manufacturer could market a drug narrowly within one or more rare-disease indications for many years—protecting it from negotiation the entire time—all the while expanding into a broader population where most of its revenue is earned. CMS' proposal resolves at least two scenarios that needed resolution. First, a drug originally designated or approved for one or more rare conditions, which otherwise qualified for the Orphan Drug Exclusion, then received FDA approval for a broader non-orphan indication that was later withdrawn. Left unresolved, the ambiguity over whether the drug regains Orphan Drug Exclusion status once the non-orphan approval is withdrawn could delay negotiation eligibility, and the Medicare savings that come with it, years or even decades beyond what Congress intended.

CMS relies on several sources for determining Orphan Drug Exclusion eligibility, including the FDA Orphan Drug Product designation database, which does not record designation withdrawals prior to August 12, 2013. This creates a second category of ambiguity, where CMS could therefore lack an accurate withdrawal date for some drugs—the date needed to calculate when a drug stops qualifying for the Orphan Drug Exclusion.

As noted above, CMS has proposed two provisions in this rule to clarify eligibility and applicability of the Orphan Drug Exclusion: For a drug or biologic that *did* qualify for the Orphan Drug Exclusion at initial approval/licensure, (1) the 7-year (small-molecule) and 11-year (biologic) negotiation-eligibility clocks start running from the first day the drug ceases to meet the exclusion criteria—determined as the earlier of: FDA approval of a non-rare-disease indication (regardless of later withdrawal of that approval), or withdrawal of the orphan designation itself; and (2) use the August 12, 2013 default date for the 7-year (small-molecule) and 11-year (biologic) negotiation-eligibility clocks, where applicable.

By fixing clear, objective criteria and a date for when the exclusion ends and the countdown begins, CMS' proposals clarify ambiguity in the existing policy. We support CMS setting a defined, verifiable threshold for when orphan exclusion status ends, removing much of the room for manufacturers to time indication expansions or designation withdrawals in ways that stretch out exclusion-driven delay, and it is appropriate that CMS has flagged the Orphan Drug Exclusion as one of the eligibility-related provisions with potentially meaningful long-run economic consequences and manufacturer gaming.

3. Codified process for determining "Bona Fide Marketing"

We generally support the process and timetable proposed at § 429.130 for determining whether the manufacturer of an approved generic drug or licensed biosimilar is engaged in Bona Fide

Marketing of that product. Reflecting the statutory requirement that a generic or biosimilar version of a reference branded product must be both approved (or licensed, as applicable) "and marketed"[4] to remove that reference branded product from the list of QSSDs, this provision makes clear what information beyond FDA approval alone is needed to establish that Bona Fide Marketing exists.

In guidance documents for previous IPAYs, CMS had stated that it planned to review monthly relevant information and each month determine whether a generic or biosimilar of a selected drug was "bona fide marketed" based on that information. In this proposed rule, CMS will make a determination on whether a generic or biosimilar of a selected drug is "bona fide marketed" on specific dates that are key statutory milestones for the primary drug manufacturer of the selected drug. Under this proposal, the monthly review of information will begin in March of the year of the negotiation period until November 1 of the year that is two years prior to the initial IPAY, and once the negotiation period concludes, the information will be reviewed biannually in March and October. This timing matters to the primary drug manufacturer of the selected drug. A generic or biosimilar market launch that occurs after a drug has already been selected for the MDPNP or even while negotiations are underway can still affect whether that drug remains subject to negotiation. The proposed provision also makes clear that commercial execution, not any single utilization threshold, is what actually counts—reliable distribution and real sales volume will carry more weight than hitting a specific prescription count or market-share figure. Notably, CMS deliberately declines to establish a safe-harbor threshold that manufacturers could point to as automatically satisfying the standard, relying instead on a totality-of-the-circumstances review that preserves the agency's flexibility to look past superficial compliance.

We view this as striking a sensible balance: it prevents manufacturers from avoiding negotiation through token or paper launches designed only to trigger the exclusion, while still ensuring that legitimate generic and biosimilar competition can displace negotiated pricing once that competition has genuinely begun. A bright-line, easily engineered-around threshold would have invited exactly the kind of gaming this provision is designed to prevent, and CMS is right to avoid it.

4. New method for one-time therapies

We share CMS' objective in proposing to develop a new methodology under the proposed § 429.415(a)(2) for calculating a 30-day equivalent supply for drugs typically administered only once, such as gene therapies, certain vaccines, and some oncology treatments. This is because that methodology drives key elements of the negotiation process, including the initial offer and calculation of the ceiling for the Maximum Fair Price (MFP) for a selected drug.

[4] Social Security Act § 1192(e).

As proposed, the one-time therapy provisions are surprisingly narrow, as the methodology acknowledges vaccines and oncology treatments but does not create a special negotiation framework for gene therapies or curative therapies. Instead, they solve a technical problem in CMS' MFP methodology.

This reliance on a technical fix aimed at using an established method to address a substantively different set of drugs (cell and gene therapies are not similar to antibiotics) potentially introduces new technical issues and opportunities for gaming by manufacturers. Instead, a special pricing rule would be preferred and would be increasingly important as cell and gene therapies proliferate.

5. Temporary Floor for Small Biotech Drugs

We write to express our appreciation for the agency's thoughtful treatment of the Temporary Floor for Small Biotech Drugs at § 429.440. As the proposed rule notes, this policy is new for IPAY 2029, following Congress' instructions in Section 1194(d) of the Act. CMS has rightly identified a key issue regarding the implementation of this statutory provision on which the statute is silent: how to apply Section 1194(b)(2)(F)(ii) in a situation where the ceiling, as otherwise specified in statute and calculated, is below the Temporary Floor for Small Biotech Drugs. Because it is possible to envision how such a situation might arise, it is important for CMS to propose policy solutions to such a scenario.

We agree with CMS' goal of "ensur[ing] the negotiation process gives effect to the Temporary Floor for Small Biotech Drugs provision at section 1194(d) of the Act that establishes a specific limitation to the general rules for MFP negotiations." CMS is right to first determine whether any adjustments are necessary. If not—if the unadjusted ceiling is greater than or equal to the Temporary Floor—CMS ought to use its consistent methodology and process.

But if the Temporary Floor is greater than the unadjusted ceiling, we encourage CMS to consider simply raising the ceiling to be equal to the Temporary Floor rather than conduct the agency's proposed stepwise adjusted ceiling calculation. Raising the ceiling to be equal to the Temporary Floor is most likely to give effect to Congress' direction in Section 1194(b)(1) to "aim[] to achieve the lowest maximum fair price for each selected drug." CMS' proposed first-step approach of considering only the average non-Federal Average Manufacturer Price (non-FAMP) for such drug for the prior year to the selected drug publication date (the amount described in Section 1194(c)(1)(C)(ii)(II) of the Act), if it does create a ceiling that is higher than the Temporary Floor, could result in a higher MFP. We do not believe this approach would qualify as disregarding the ceiling but would rather establish a ceiling and simultaneously give effect to the Temporary Floor for Small Biotech Drugs provision at Section 1194(d) of the Act, which

functions to provide increased predictability regarding cash flow to companies falling into this category.

6. Regulatory Impact Analysis (RIA)

With the transition from guidance to rulemaking, this cycle of the program is the first to feature an RIA. However, without decomposing the separate effect of the MDPNP from benefit redesign, the manufacturer discount program, and secular trends in drug utilization, a reader can incorrectly conclude that negotiation itself increases federal Part D spending through 2030, which is almost certainly not what the actuarial model is showing. The RIA must reconcile the inconsistent and misleading treatment of the various components of the IRA and its interactions with the structure of the Part D program.

This RIA is not structured as a traditional "Table 1: Summary of Costs and Benefits" rulemaking where CMS estimates large new savings from the regulation itself. Instead, the RIA introduces three different counterfactuals: (1) a historical estimate that considers the impact of all IRA provisions in the aggregate; (2) the specific impact of the expansion of the Orphan Drug Exclusion under the Working Families Tax Cut Act; and (3) a mostly qualitative assessment of the new fixed combination proposal in part because the main impacts occur outside the 10-year budget window (however, the RIA does not include counterfactuals that take into consideration any of the other proposed provisions).

With respect to the first counterfactual, in Table 18 and the surrounding material, CMS conflates the effects of the Medicare Part D benefit redesign of the IRA with the effects of the Negotiation Program on federal spending and uses the President's 2024 budget baseline that was developed in early 2023. The RIA's reporting of aggregate savings is confusing. For example, in its reporting of federal spending changes stemming from the MDPNP, the RIA shows increased spending for Part D as a result of the MDPNP through 2030. By doing so, the RIA in effect is attributing features of the Part D benefit redesign and out-of-pocket caps to the MDPNP. This is problematic for multiple reasons, two of which we focus on here. First, the benefit redesign is not the same as the MDPNP in that it is focused on benefit design and not price negotiations. Second, the benefit redesign was implemented prior to the proposed regulatory changes and therefore imposes a counterfactual that in large part reflects the pre-MDPNP state of the program. The result is a projection that only partly reflects the impact of the MDPNP and thus creates a misleading impact estimate. In fact, CMS reports significant and growing reductions in Medicare allowed costs associated with the MDPNP (Table 16). Table 18 also combines MDPNP as-a-whole estimates with the "narrower" perspective advanced by CMS. Therefore, the conflating of other features of the IRA with the MDPNP creates a misleading understanding about the impact of the MDPNP.

CMS acknowledges that what has happened subsequently to the implementation of the IRA differs in important ways from the conclusions projected in the original model produced in 2023. Some key developments include the following:

- Part D per-capita gross drug costs increased by more than 18% in 2025, driven substantially by GLP-1 and specialty-drug use.
- The projected MFP reductions from allowed costs are now 11.3% for the 2026 selected drugs and 18.2% for 2027—more than two percentage points larger than originally modeled.
- Actual Part D inflation rebates for 2023 exceeded $500 million, compared with the modeled $400 million.
- Part B inflation rebates, originally assumed to be negligible, were $14 million for 2023 and $121 million for 2024.
- CMS still lacks complete data on 2025 Direct and Indirect Remuneration (DIR) and the Manufacturer Discount Program and says it will be difficult to attribute later spending changes among the benefit redesign, MFPs, utilization growth, and other provisions.

This means Table 18 should not be interpreted as CMS' current best estimate of the prospective impact of the regulation by itself or even of the MDPNP alone. The implication is that several important factors affecting Part D spending that go beyond the MDPNP are reflected in Table 18.

As a second counterfactual, the RIA considers the 2025 reconciliation legislation that expanded the Orphan Drug Exclusion. CMS addressed these changes by taking into account the reduced set of negotiation-eligible drugs. In making projections, CMS assumed that the composition of orphan and non-orphan drugs would remain constant in the future and thus assumed no behavior changes among manufacturers. The counterfactual used was the mid-session 2026 baseline without the orphan-drug amendments, a reasonable basis for comparison. CMS also removed from its analysis drugs that would be newly exempted from the MDPNP projections.

Regarding the third counterfactual and the fixed combination drug proposal, CMS does not provide a quantitative estimate of the net difference because both the earlier-negotiation benefit and the possible earlier-deselection cost largely occur outside the 10-year budget window. In addition, CMS claims it lacks a credible drug-level forecast that far ahead. The implied counterfactual in the qualitative discussion is the fixed combination policy as applied in IPAYs 2026-2027.

Importantly, the main point of RIAs is to forecast the anticipated consequences of a regulation. The Office of Management and Budget (OMB) Circular A-4, Regulatory Impact Analysis: A Primer, states the following:

"Executive Orders 13563 and 12866 require agencies to provide to the public and to OMB a careful and transparent analysis of the anticipated consequences of economically significant regulatory actions. This analysis includes an assessment and (to the extent feasible) a quantification and monetization of benefits and costs anticipated to result from the proposed action and from alternative regulatory actions. Executive Order 13563 specifically requires agencies 'to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'"

As a result of these assumptions, the RIA is hard to interpret as an overall estimate of the law as it stands in 2026. The layering of multiple counterfactuals and the inclusion of policies and trends beyond the MDPNP serves to obscure the true impact of the negotiation program. Since this is the first public CMS assessment of the MDPNP, a more appropriate counterfactual would be to compare Medicare spending with the MDPNP to Medicare spending absent the MDPNP, accounting for the benefit redesign and other IRA policies separately. The current RIA serves to minimize the impact of the MDPNP, and instead the aggregate impacts of the IRA appear in Tables 16 and 18.

Sincerely,

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