August 17, 2026

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

Submitted via regulations.gov

RE: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program; Proposed Rule (CMS-4215-P)

Dear Administrator Oz,

The undersigned members of the MAPRx Coalition (MAPRx) appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule to codify the Medicare Drug Price Negotiation Program (MDPNP) for Initial Price Applicability Year (IPAY) 2029 and subsequent years (CMS-4215-P).

MAPRx is a national coalition of beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. The coalition has championed policies in Part D that improve the affordability of medications and beneficiary access to those medications, including provisions of the Inflation Reduction Act (IRA) that establish an out-of-pocket cap in Part D and the Medicare Prescription Payment Plan. We are committed to ensuring that the implementation of these and other elements of the IRA are informed by the experiences and needs of beneficiaries living with chronic diseases and conditions.

MAPRx has provided comments on prior MDPNP guidance cycles and has consistently urged CMS to implement the program in ways that deliver genuine, durable improvements for patients, not just nominal formulary inclusion. The transition from annual sub-regulatory guidance to binding regulation is a significant structural milestone. Codification creates enforceable standards. MAPRx urges CMS to use this rulemaking opportunity to embed meaningful patient protections in the regulatory text.

Our comments address four areas: (1) formulary access and utilization management protections for selected drugs; (2) the codified patient engagement process; (3) transparency requirements for the Maximum Fair Price (MFP) explanation; and (4) treatment of new fixed combination drugs with a new route of administration.

I. Formulary Access and Utilization Management Protections for Selected Drugs

The proposed rule codifies the requirement that Part D plan sponsors include selected drugs with a MFP in effect on their formularies. CMS also codifies its existing formulary review process, under which it assesses instances of adverse tiering, step therapy requirements, and more restrictive prior authorization (PA) applied to selected drugs relative to non-selected drugs in the same class. During this review, plans are required to provide "reasonable justification" for identified variances.

MAPRx supports formulary inclusion of selected drugs but has argued, across multiple prior guidance cycles, that a monitoring-based compliance model is inadequate to guarantee that beneficiaries can access their prescribed medications. Formulary listing is a necessary condition for access, but not a sufficient one. Plans facing increased financial liability under the Part D redesign have strong incentives to manage utilization of selected drugs through PA requirements, step therapy protocols, and adverse tiering. The proposed rule preserves these tools for drugs with an MFP in effect.

MAPRx recommends that CMS:

- **Codify enforceable limits on utilization management for selected drugs.** "Reasonable justification" review during the bid process does not constrain plan behavior during the plan year. The final rule should establish that PA and step therapy applied to a selected drug must be clinically grounded and no more restrictive than requirements applied to therapeutic alternatives within the same class, with clear standards that CMS can enforce throughout the year, not only at the bid review stage.
- **Require public reporting on utilization management outcomes for selected drugs.** CMS should require plan-level public reporting on PA and step therapy exception request approval and denial rates, appeal outcomes, and time-to-determination for selected drugs. Reported data should be publicly available in a format accessible to beneficiaries and patient advocacy organizations.
- **Establish an expedited review process for utilization management barriers.** CMS should codify a mechanism by which beneficiaries or their representatives can flag access barriers on selected drugs for timely CMS review, with defined response timelines and corrective action authority.
- **Formulary Review Transparency.** The proposed rule codifies CMS's formulary review process, but that process remains largely opaque to beneficiaries and the patient organizations that advocate on their behalf. Stakeholders can observe the consequences of restrictive formulary design and utilization management such as delayed access, step therapy requirements and coverage denials but have limited visibility into how CMS evaluates plan compliance, what deficiencies it identifies, and what corrective action looks like when a plan falls short.

  MAPRx urges CMS to require standardized public reporting on key access indicators for selected drugs, including plan-level prior authorization and step therapy exception request

approval and denial rates, time-to-determination, and appeal outcomes. CMS should also publish a plain-language account of its formulary review criteria and oversight process for selected drugs, including the standards it applies to assess adverse tiering and utilization management restrictions, so that beneficiaries and patient organizations can evaluate whether CMS oversight is functioning as the rule intends.

II. Patient Engagement in the Negotiation Process

The proposed rule codifies a patient engagement structure that includes patient-focused roundtable events open to patients, patient advocacy organizations, and caregivers; a public data submission window for information about selected drugs, unmet medical need, and impacts on specific populations; and a clinical town hall. MAPRx supports the inclusion of these elements in the regulatory framework.

However, the proposed milestones note that "additional information about these public engagement sessions will be shared in the future." Leaving the design of these sessions to future agency discretion, even as the process is being moved into binding regulation, is inconsistent with the purpose of codification. If the patient engagement process is important enough to codify, the final rule should establish minimum enforceable standards, not simply affirm that engagement will occur in some form to be determined later.

MAPRx has raised specific concerns about the existing engagement model through prior comment cycles, and we appreciate CMS taking steps to improve the process as some of the most recent listening sessions were well executed according to patient organizations that participated. However, the patient engagement experience was inconsistent. In general, large-format listening sessions do not enable the exchange necessary for CMS to understand the heterogeneity of patient experience across disease populations. Patients who cannot participate in live sessions due to disability, language barriers, health status, or access constraints are systematically underrepresented. And participant selection criteria have not been made transparent to patient organizations, limiting their ability to identify and prepare appropriate representatives.

MAPRx urges CMS to include in the final rule minimum process standards for patient-focused engagement, including:

- **Bidirectional session formats.** Roundtable events should be designed to enable genuine exchange, including structured question-and-answer opportunities, rather than one-way testimony. CMS should specify that at least a portion of patient engagement sessions will use smaller group formats that allow for dialogue.
- **Written and recorded submission alternatives.** Participants who cannot attend live sessions should have a defined pathway to submit written or recorded input. The public data submission window partially addresses this, but it should be explicitly structured to accept patient experience accounts, not only quantitative data. The timeline of approximately 30 days is challenging for patient organizations to sufficiently prepare their data analysis and organize appropriate patient responses. We ask that at least 60 days be provided.
- **Transparent participant selection.** CMS should publish its participant selection criteria in advance and provide patient organizations with the opportunity to recommend appropriate participants for their respective disease communities. After, CMS should publish the participation in a non-identifiable format including number of participants that applied,

total accepted and what type of participant they were (patient, caregiver, advocacy organization, etc.).

- **Accessibility accommodations.** The final rule should require that engagement sessions be accessible to individuals with disabilities and that translation and interpretation services be available for participants with limited English proficiency.

Codifying the existence of patient engagement without codifying minimum quality standards risks institutionalizing an inadequate process. The final rule should set a floor that reflects genuine engagement, not just the form of it.

III. Transparency in the MFP Explanation

The proposed rule includes a welcome new element: CMS will publish whether an MFP was not agreed upon for a selected drug and the reason a drug ceases to be a selected drug. MAPRx supports this additional transparency and urges CMS to extend the same principle to the published explanation of the MFP itself.

CMS currently publishes a narrative MFP explanation following the conclusion of negotiations. MAPRx has consistently urged CMS to use that explanation to communicate how and to what extent patient input was considered in the negotiation. This disclosure is essential for two reasons:

1) It demonstrates to patients and patient organizations that their participation in roundtables and data submission processes is genuinely consequential, not procedural.
2) It enables CMS to build trust with the advocacy community whose engagement the program depends on for diverse and representative input.

MAPRx urges CMS to require that the published MFP explanation include a narrative description of how patient engagement was considered in developing the negotiation. This requirement need not disclose confidential commercial or financial information. It should address, at a minimum, the patient-reported experience with the selected drug and its therapeutic alternatives that informed CMS's understanding of the drug's clinical and quality-of-life value.

Without this requirement, the MFP explanation will continue to describe the outcome of the negotiation without accounting for the process by which beneficiary perspectives contributed to it. Codification is the appropriate moment to close this transparency gap.

IV. Treatment of Fixed Combination Drugs with a New Route of Administration

The proposed rule would modify how CMS identifies potential qualifying single source drugs at proposed § 429.125(b)(4)(i). Under this proposal, a fixed combination drug that adds an active moiety or active ingredient enabling an alternative route of administration for an existing active moiety or active ingredient would generally be treated as the same qualifying single source drug as the original product, for purposes of both drug selection and MFP effectuation.

MAPRx is concerned that the proposed policy does not distinguish between formulation changes made to evade the Negotiation Program and formulation changes that give beneficiaries a genuinely different and clinically valuable way to take their medication. A change in route of administration, such as a shift from intravenous infusion to a subcutaneous injection a beneficiary can administer at home, can meaningfully reduce the burden of treatment for beneficiaries

managing chronic conditions, particularly those with mobility limitations, transportation barriers, or caregiving responsibilities that make frequent infusion visits difficult.

Treating such reformulations as inseparable from the original product for negotiation purposes, without regard to the clinical benefit the new route of administration provides, risks weakening the incentive to bring these patient friendly options to market.In evaluating the clinical value of an alternative route of administration, CMS should also consider its potential effects on treatment burden, adherence and continuity of care, site-of-care requirements, transportation and caregiver demands, and patient preference.

MAPRx opposes the proposed fixed combination drug policy and urges CMS to abandon it in favor of an approach that preserves separate qualifying single source drug (QSSD) classifications for a Food and Drug Administration (FDA)-approved fixed dose combination therapies, including those in which an added ingredient enables a clinically meaningful alternative route of administration.

Aggregating such formulations with the original QSSD fails to account for the distinct therapeutic value they deliver to beneficiaries and conflates program integrity concerns with genuine clinical innovation. If CMS declines to withdraw the proposal, it should establish objective, transparent criteria that distinguish formulation changes posing genuine program integrity risk from those that offer beneficiaries a meaningfully different treatment experience and should seek patient and caregiver input on the value of alternative routes of administration before finalizing this policy.

Conclusion

MAPRx commends CMS for the decision to codify the MDPNP in regulation and recognizes the substantial implementation work this transition represents. The program has already delivered meaningful savings for Medicare beneficiaries and MAPRx is committed to ensuring that those savings translate into durable, equitable access.

Thank you for the opportunity to comment. MAPRx welcomes continued engagement with CMS on the implementation of the MDPNP. For questions related to MAPRx or these comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

Sincerely,

AiArthritis
ALS Association
American Association on Health and Disability
American Association on Health and Disability
American Cancer Society Cancer Action Network (ACS CAN)
American Kidney Fund
Arthritis Foundation
Autoimmune Association
Blood Cancer United
Coalition of Skin Diseases
Derma Care Access Network
Eosinophilic & Rare Disease Cooperative
Foundation for Sarcoidosis Research
GO2 for Lung Cancer
HIV+Hepatitis Policy Institute

Immune Deficiency Foundation
Lakeshore Foundation
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Mental Health America
Muscular Dystrophy Association
National Council on Aging
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