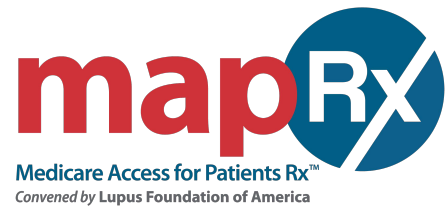


April 14, 2023



The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20510

Submitted via IRAREbateandNegotiation@cms.hhs.gov

RE: Medicare Drug Price Negotiation Program Guidance

Dear Administrator Brooks-LaSure:

The MAPRx Coalition (MAPRx) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments regarding the implementation of the Medicare Drug Price Negotiation Program (MDPNP) for initial price applicability year (IPAY) 2026, published March 15, 2023.¹

Our group, 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 undersigned members of the MAPRx Coalition are pleased to provide CMS with our official commentary in response to your efforts to negotiate maximum fair prices (MFPs) for certain high-expenditure, single-source drugs and biological products.

MAPRx appreciates the opportunity to comment on how Medicare intends to negotiate with pharmaceutical manufacturers for lower prices on selected high-cost drugs. MAPRx believes it is critically important for beneficiaries to have access to innovative therapies and wants to ensure that MDPNP efforts do not exacerbate barriers to patient access.

MAPRx thanks CMS for seeking feedback on the negotiation process guidance, a step that was not explicitly required in the Inflation Reduction Act (IRA) statute. However, we remain concerned about the short 30-day comment period for the initial guidance, especially without knowing which products will be negotiated. The comment period provides little time to review the guidance and to consider and draft constructive feedback on the process by which CMS will negotiate drug prices for the first time in its history. Additionally, the inability of stakeholders to engage CMS while the agency is developing proposed regulations further limits the time permitted to provide input.

While we would have preferred an official Notice and Comment opportunity that would have facilitated an agency response directly to stakeholder feedback, we appreciate the opportunity

¹ Seshamani M. Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments. March 15, 2023. Accessed March 30, 2023. <https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf>

to share our concerns related to the MDPNP guidance. Overall as a coalition, we are focused on ensuring the following:

- Patient organizations have ample opportunity and ability to provide feedback on the negotiation process;
- CMS is transparent into how the agency factors external data into its final decisions (including the methodology deployed by the agency);
- The agency maintains access to a wide range of drugs within Part D and looks to minimize affordability challenges; and
- The agency establishes appropriate guardrails and ongoing oversight processes to continually evaluate the program for the purposes of refining when needed.

To that end, MAPRx is submitting comments on the following issues CMS addressed in the initial guidance:

- Highlighting the need for patient input to effectively maintain oversight and explore necessary program changes
- Maintaining beneficiary protections while implementing the new process
- Excluding orphan drugs from qualifying single-source drugs
- Excluding the utilization of Quality-Adjusted Life-Years in the negotiation process
- Offering feedback on future program guidance
- Reviewing the evidence about therapeutic alternatives for the selected drug
- Ensuring clear communication regarding the explanation for the MFP
- Exploring the future operation of the MDPNP
- Offering additional comments on the drug selection process

Patient Input Essential to Oversight and Continuous Improvement

As CMS initiates the implementation process, MAPRx requests the agency provide robust oversight to prevent unintended adverse patient impacts. Given the significant effect this new program and other changes, such as the redesign of the Part D benefit, will have on the drug delivery system, CMS must have proper systems in place to monitor impacts to ensure the program has the intended effect of increasing access and affordability for patients. At a minimum, CMS should monitor whether beneficiaries actually realize the expected savings, are not steered toward negotiated drugs inappropriately, do not face increased utilization management on either negotiated or non-negotiated drugs, and do not face other barriers to access.

In addition, it will be important for CMS to monitor the impact of negotiation on launch prices, inadvertent incentives for plans to prefer higher-priced drugs if they are able to achieve greater rebates (or inappropriate steering toward higher-priced drugs when Part B negotiation begins, due to higher provider fees), and disincentives to follow-on research on additional indications or new formulations that can demonstrate additional benefit such as greater adherence or reduced side effects.

Given that this guidance applies to the first year of negotiation, CMS will likely need to implement a mechanism for making needed adjustments. As such, we recommend CMS explore a formal process for seeking input from patients on the impacts of IRA implementation following the full implementation and on an ongoing basis.

MAPRx also requests guidance on how the patient community can best engage via the various information collection requests (ICRs). MAPRx appreciates the agency engaging with various stakeholder groups and is hopeful that the collaboration will continue with beneficiaries. To that end, we recommend CMS consider convening stakeholder panels or establishing other mechanisms to engage the beneficiary community and inform key decision points, including to obtain patient perspectives related to therapeutic alternatives and therapeutic advances, unmet need, considerations related to subpopulations and minorities, and patient experience and preference. MAPRx is committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities and welcomes the opportunity to provide CMS with patient-level data to ensure the best outcomes for patients.

Maintaining beneficiary protections while implementing the new process

MAPRx emphasizes the need for beneficiary protections and access to care while CMS is undergoing the new drug price negotiation process. We appreciate the Inflation Reduction Act's provision requiring all Part D plans to cover each drug with negotiated MFPs for all years for which the price is in effect during the price-applicability period. This provision helps ensure beneficiaries will benefit from the negotiation process and have access to the lowest-price drugs. MAPRx encourages CMS to monitor Part D plans to ensure beneficiaries have access to all negotiated drugs and provide opportunities to comment on beneficiary protections in the future. In addition, we urge CMS to provide strong monitoring and oversight of beneficiary access to both negotiated and non-negotiated drugs. For example, changes in formularies, tiering and cost sharing can impact a beneficiaries' ability to access prescription drugs under Part D.

Specifically, we seek clarification on CMS' interpretation of the requirement that negotiated drugs be covered by plans and if Part D plans will be allowed to apply utilization management (UM) tools or high cost sharing for the negotiated drugs. The initial guidance did not address UM techniques (e.g., step therapy, prior authorization, etc.) or cost-sharing requirements employed by Part D plans with respect to drugs with negotiated MFPs. While the patient community is incredibly supportive of the Part D redesign and out-of-pocket cap, we understand plans will face higher liability moving forward and therefore likely restrict coverage and/or access. Such UM techniques and cost-sharing requirements can create significant barriers and increase costs for patients by delaying the start or continuation of necessary treatment and negatively affecting patient health outcomes.^{2,3,4} Given this likely plan reaction to the higher liability, it is more important than ever that CMS create guardrails to ensure access to medicines by limiting burdensome barriers such as prior authorization and step therapy. By defining coverage requirements, CMS reduces the risk of plans denying coverage for products vital to a patient's comprehensive care plan. We also believe ensuring open access to negotiated drugs is simply the right thing to do. If a plan is receiving a lower price based on a maximum *fair* price, the benefit should be fully conveyed to beneficiaries through *fair* access. Conversely, it is crucial

² American Medical Association. Prior Authorization and Utilization Management Reform Principles. Accessed April 4, 2023. <https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf>

³ O'Neil A, Calderbank S, Brown J, et al. Quantification of Utilization Management Barriers for Patients Initiating Therapy to Lower Lipid Levels. *JAMA Netw Open*. 2022;5(11):e2240513. Accessed April 4, 2023. doi:10.1001/jamanetworkopen.2022.40513

⁴ US Congress. House of Representatives. Utilization Management: Barriers to Care and Burdens on Small Medical Practices. 116th Cong, 1st sess. September 11, 2019. Accessed April 4, 2023. <https://www.govinfo.gov/app/details/CHRG-116hrg37560/CHRG-116hrg37560>

that CMS does not allow plans to prefer non-negotiated drugs by applying utilization management on negotiated drugs.

Excluding orphan drugs from qualifying single-source drugs

MAPRx appreciates the agency's openness for additional approaches on the orphan drug exemption. Our coalition is concerned the new law may hinder innovation, particularly for orphan drug indications. The Orphan Drug Act and other statutes, regulations and guidance create incentives to encourage the development of treatments for rare diseases. Rare diseases need incentives to encourage manufacturers to invest in developing treatments, however, MAPRx is concerned that the implementation of the IRA may undermine these incentives.

The law states CMS must exclude from price negotiations a drug for only one rare disease or condition and for which the only approved indication (or indications) is for such disease or condition. Unfortunately, if a manufacturer obtained an orphan designation to conduct research into treatment for another rare disease, the drug could be subject to price negotiation, even if it only has one approved indication. The law and its implementation thus remove the incentive for manufacturers to even conduct basic research and development into multiple rare diseases.

This disincentive has already been activated. Two manufacturers have stated they have cancelled further research of drugs, due to the disincentives built into the law and its implementation.⁵

MAPRx is concerned about the potential impact to investments in rare disease, and patients will suffer the most from such decisions.

Excluding the utilization of Quality-Adjusted Life-Years in the negotiation process

MAPRx is pleased that the Inflation Reduction Act (IRA) prohibits CMS from using the quality-adjusted life year (QALY) metric in the negotiation process. Any evidence that values extending the life of some individuals less than extending the life of other individuals based on disability status or age is completely inappropriate. All patients deserve to be treated equally, and thus we laud CMS' adherence to the statute and decision to separate out and exclude QALY metrics from evaluations of research that otherwise factor in QALYs. However, we are concerned that CMS may not effectively eliminate QALYs from analysis, or that CMS may over-exclude analyses that are otherwise helpful in establishing the value of a drug. Thus, we request that CMS offer more clarity into exactly how the agency will exclude QALY-based metrics from analysis of certain evidence. We also request that CMS highlight when and how the agency removes QALY-based metrics from consideration in MFP justification documentation. MAPRx is concerned that, unless CMS outlines a rigorous process for how the agency will consider evidence stemming from the use of QALY so as to not discriminate against individuals who are elderly, disabled, or terminally ill, such evidence could be inadvertently used that would be disadvantage said populations.

⁵ Endpoints News. Updated: Eli Lilly blames Biden's IRA for cancer drug discontinuation as the new pharma playbook takes shape. November 1, 2022. Accessed April 11, 2023. <https://endpts.com/eli-lilly-rolls-snake-eyes-as-it-axes-two-early-stage-drugs-including-a-40m-cancer-therapy-from-fosun/>

Fierce Pharma. As Amvuttra makes inroads in ATTR, Alnylam scraps heart disease trial interim analysis, rethinks another rare disorder plan. October 27, 2022. Accessed April 11, 2023 <https://www.fiercepharma.com/pharma/amvuttra-makes-inroads-attr-alnylam-scraps-heart-disease-trial-interim-analysis-rethinks>

While it is clear both in the statute and this guidance that QALYs will not be used as a base for evaluations, CMS requested input on what other measures might be appropriate or inappropriate. While we do not have a position on a specific measure, we do think that it is important that CMS rely on more than a single metric and explore a wide variety of sources by taking a holistic approach to this data. Patient value is multi-faceted, and any attempts to distill important dimensions of patient value and benefit into a single number is fraught.

Reviewing the evidence about therapeutic alternatives for the selected drug

MAPRx appreciates CMS considering different methods to evaluate the value of a prescription drug for patients. However, MAPRx cautions that this approach may not be appropriate for many drugs due to the difficulty in determining equivalence among drugs and biologics. Many times, it can be difficult to determine whether one pharmaceutical intervention is better than another for a patient. Throughout the coalition's existence (since 2005), we have consistently stated that the ultimate decision between available therapies should be left to the physician and the patient for this very reason. Patient experience needs to inform determinations of therapeutic equivalence. Additionally, while a selected drug may have therapeutic alternatives, the selected drug and any alternatives may not share the same specific indication or be used by the same population groups. Finally, some drugs may lack therapeutic alternatives as they are the only therapies in a given class to treat a specific condition. While MAPRx welcomes robust competition and options for patients, we support patient access to these critical therapies.

MAPRx is concerned about the unintended consequence that this specific provision may have on future access. Choosing lower-cost, therapeutic alternatives to drive down the price of the selected drug could disincentivize manufacturers from investing in therapies to treat specific indications or specific populations. With the potential to be linked to a lower-cost product with a questionable efficacy in a narrower population, manufacturers may opt against focusing on innovations for certain population groups or exploring additional indications to determine if their products have further benefits.

Offering feedback on future program guidance

We appreciate the opportunity to comment on initial program guidance for IPAY 2026 and seek clarification on processes for soliciting feedback moving forward. We request visibility into the opportunities to provide input into adjusting future program guidance and if there will be a comment opportunity to inform negotiation for IPAY 2027 and beyond. We believe that CMS may need to reevaluate its methodology for various pieces of the negotiation process, including aggregating drugs to determine MFP. As this is a new program implemented in a non-traditional manner, we believe CMS should be nimble and responsive to feedback from stakeholders as the policy is implemented year over year. To that end, CMS should establish a meaningful process for 1) patients and other stakeholders to provide consistent feedback on the experience of IPAY 2026, and 2) CMS to evaluate policy decisions made for the initial year of negotiation and incorporate necessary changes quickly for future years.

Ensuring clear communication regarding the explanation for the MFP

The explanation for the MFP will be a critical tool in the continuous improvement of the negotiation program, as well as a tool for the patient advocacy community to learn and improve our ability to participate in the process. We urge CMS to assure that these explanations are clear, accessible, and transparent. We also ask that CMS include critical information about what data was used to develop the MFP and how specifically it was used. We are especially

interested in information about how patient experience data was incorporated. Including this information in the explanation will help patient advocates develop the most useful data for future negotiations.

Exploring the future operation of the MDPNP

MAPRx respectfully requests further information on how the 2026 negotiation process will inform Part B negotiations in future years. Such information will enable stakeholders to have greater clarity into the future operations of the MDPNP and to plan accordingly.

Offering additional comments on the drug selection process

Although we are aware that you are issuing Section 30 on drug selection as final, we have a few comments we hope CMS will consider as the agency implements the drug-selection process for negotiation.

For example, we are concerned about the effects that the aggregation of drugs with the same active moiety or active ingredient in the selection process could have on subsequent research. We worry that aggregation could disincentivize research into additional indications or potential reformulations that improve patient adherence and/or outcomes. Without appropriate guardrails such as more nuanced definition, this initial guidance may discourage these types of improvements. While we understand the desire to eliminate potential gaming of extending patent life or time before negotiation, we fear this may be an overly broad approach that does not consider the patient perspective on whether reformulations demonstrate an improvement to patient care and feel there are better approaches to address this issue. We caution the agency against advancing this approach without appropriately assessing the impact it may have on incremental treatment improvements that can greatly benefit patients. If CMS is unable to reconsider this approach, we request that you undertake future notice and comment processes with adequate time for stakeholders to consider the impact of selection criteria as the negotiation process is implemented.

Conclusion

We strongly uphold that decisions on value are best taken when patient organizations can engage in the process and when patients are not limited by coverage policies that restrict access to products that best meet their individual needs. Thus, we urge CMS to carefully consider these comments for this and future guidance and allow for patient voices to be heard and emphasized throughout the negotiation process.

Thank you for your consideration of comments on the initial guidance of the implementation of the MDPNP for calendar 2026. The undersigned members of MAPRx appreciate your leadership to improve beneficiaries' access to products in Medicare Part D. For questions related to MAPRx or the above comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

Allergy & Asthma Network
Alliance for Aging Research
Alliance for Patient Access
ALS Association
American Association on Health and Disability
American Kidney Fund

Association of Hidradenitis Suppurativa and Inflammatory Diseases
Color of Crohn's and Chronic Illness
COPD Foundation
Derma Care Access Network
Epilepsy Foundation
GO2 for Lung Cancer
HealthyWomen
Lakeshore Foundation
LUNGeivity Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Muscular Dystrophy Association
National Kidney Foundation
National Psoriasis Foundation
Partnership to Advance Cardiovascular Health
RetireSafe
The AIDS Institute
The Headache & Migraine Policy Forum