Center for Innovation
& Value Research

June 26, 2025

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

RE: Draft Guidance for the Medicare Drug Price Negotiation Program:
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

Dear Administrator Oz:

The Center for Innovation & Value Research (Center) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services' (CMS) draft guidance for the Medicare Drug Price Negotiation Program (DPNP) for initial price applicability year (IPAY) 2028 and manufacturer effectuation of the maximum fair price (MFP) in 2026, 2027, and 2028.

The Center is a 501(c)3, non-profit research organization committed to advancing the science, practice, and use of patient-centered health technology assessment (HTA) to support decisions that make healthcare more meaningful and equitable. Founded in 2017, the Center's membership includes researchers, patients, payer/purchasers, clinicians, and innovator stakeholder communities. The Center's work emphasizes collaboration and exploration of new solutions in pursuit of a U.S. learning healthcare system supported by patient-centered HTA and focused on high-quality, efficient, innovative, and accessible care for all people and communities.

As described in our submitted comments on Medicare DPNP draft guidance in previous years, our work is guided by our Principles for Value Assessment.[1] These principles apply not only to the narrow context of HTA but are also fundamental to building a patient-centered health system where value is defined by its impact on patients and their families and drives decision making. We continue to believe the implementation by CMS of the Medicare DPNP should be grounded in these principles, the foremost among them being patient-centricity, transparency, and methodological rigor. This commitment to patient-centered value is reflected in the comments and recommendations offered below.

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[1] https://valueresearch.org/who-we-are/value-principles/

We commend CMS for its ongoing efforts to improve the DPNP while balancing the competing needs, concerns, and requests of diverse stakeholder groups and ensuring the program adheres to the statutory requirements laid out in sections 1191 through 1198 of the Social Security Act, as added by sections 11001 and 11002 of the Inflation Reduction Act (IRA). The current draft guidance for year 2028 represents a significant expansion of the program, especially in the broadening of negotiations to include drugs covered under Medicare Part B and the addition of guidelines for renegotiation of previously selected drugs. While these new dimensions of the program warrant scrutiny, we encourage CMS to continue to improve all program aspects. To that end, we offer the following recommendations.

Recommendation 1: Publish explanations of MFP determinations that are comprehensive, consistent, and detailed.

As described in section 60.6.1 of the draft guidance, Section 1195(a)(2) of the IRA requires CMS to publish explanations for the final MFPs prior to their initial applicability year. This requirement serves a critical role in ensuring program transparency, providing the only published visibility into the methods, evidence, decision processes, and overall approach used by CMS in implementing a "qualitative approach" to evaluating selected drugs (section 60.3.3.1). The lack of specificity in previous guidance documents has been a source of significant concern for the Center and others, but published explanations of MFP determinations promised an opportunity to understand and provide feedback on the methods employed by CMS.

The public comment period for the previous draft guidance closed prior to release of explanations for MFPs of the first round of selected drugs, limiting the public's ability to provide meaningful feedback. Furthermore, the published explanations for MFPs for the initial year 2026 lacked sufficient detail needed to evaluate the rigor or implications of CMS's approach. Considering this, and given the importance of these published explanations for program transparency, we strongly recommend that CMS establish the following procedures for the explanations of MFP as described in section 60.6.1:

- **Establish a formal MFP explanation template, to be used in all published explanations of MFPs, that outlines the elements each report will include.** The elements of the report should provide sufficient information to understand the methods used in literature reviews, analyses, and adjudicating submitted evidence. It should additionally include sections detailing:
    - How patients, caregivers, and other stakeholders were engaged and how the provided information was used in the MFP determination;
    - Processes and methods used to select therapeutic alternatives and outcomes; and
    - Discussion of the limitations of the evidence or analysis, or key learnings.
- **Following the release of MFP explanations, provide the opportunity for the public, particularly the academic community and patients, to submit comments and recommendations for use in improving negotiations in subsequent years.**

Recommendation 2: Strengthen and expand engagement opportunities for patients and family members.

We commend CMS for maintaining and expanding the increased emphasis on engagement opportunities, consistent with the previous years' guidance (section 60.4.1). We appreciate CMS's ongoing commitment to the continuation of these practices and encourage continued enhancement of this critical element of the DPNP.

The principal focus of the Center's work is on advancing methods for patient-centered value research, especially in the context of drugs and other health technologies. Past research conducted by the Center has highlighted methods for patient identification of key outcomes[2]; a framework for understanding patient-centered economic impacts[3]; potential approaches for incorporating multistakeholder advisory groups in quantitative analyses[4,5]; and best practices for patient engagement and inclusion. Based on this research and the Center's expertise, we recommend that CMS take the following steps:

Refine existing practices outlined in section 60.4.1 of the guidance:

- Clearly articulate how input from patients and other stakeholders will inform negotiations, and subsequently, how that input was incorporated into final decisions.
    - Public explanations for MFPs should include a dedicated section detailing the role of patient and stakeholder input in the negotiation process, incorporated as a required element of the MFP report template outlined above.
    - CMS should produce accompanying plain-language summaries of the MFP explanations, ensuring availability in multiple languages and formats to support broad public understanding.
- Continue to publish transcripts of patient roundtables and other engagement meetings with accompanying summary documents that include key takeaways.
- Conduct post-meeting participant surveys to solicit specific input on outstanding questions or clarify themes raised in engagement meetings. Include survey responses with the release of the transcripts.

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[2] dosReis S, Bozzi LM, Butler B, Xie RZ, Chapman RH, Bright J, Malik E, Slejko JF. Preferences for Treatments for Major Depressive Disorder: Formative Qualitative Research Using the Patient Experience. *Patient*. 2023 Jan;16(1):57-66. doi: 10.1007/s40271-022-00596-6. Epub 2022 Sep 19. PMID: 36121615; PMCID: PMC9483243.

[3] Malik, E., Bright, J., Ridley, E., Cope, E., & Edmunds, M. (2023). A research framework to understand the full range of economic impacts on patients and caregivers. Innovation and Value Initiative & AcademyHealth. Available at: https://valueresearch.org/wp-content/uploads/2024/01/05-2023-Economic-Impacts-Framework-Report_FINAL.pdf

[4] Xie RZ, Malik E deFur, Linthicum MT, Bright JL. "Putting Stakeholder Engagement at the Center of Health Economic Modeling for Health Technology Assessment in the United States." *Pharmacoeconomics*. 2021;39(6):631-638.

[5] Xie, R. Z., Bright, J., deFur Malik, E., & Chapman, R. H. (2021). Early reflections on stakeholder engagement in economic model development to inform value assessment. *Value & Outcomes Spotlight*.

- Embrace a broader role for patients, caregivers, and other stakeholders in line with methods for patient-centered value research. Consistent with comments submitted by the Center on previous draft guidance documents,[6] we recommend that CMS expand the role of patients beyond roundtables to provide key insights at other points in the process and with meaningful decision authority. CMS should adopt demonstrated methods for engaging patients, caregivers, and other stakeholders in identifying and weighting the importance of patient-important outcomes for use in evaluation of selected drugs and therapeutic alternatives. In addition to the research and best practices[7] developed by the Center, such an approach has also been employed with considerable success by the International Consortium for Health Outcomes Measurement (ICHOM) in the international setting.

Recommendation 3: Measure and evaluate downstream impacts on patient outcomes and access.

As the single largest purchaser of pharmaceuticals in the United States, CMS's implementation of the DPNP is expected to have significant impacts on patient access, population outcomes, system costs, and the broader healthcare market. However, the full scope and nature of these downstream impacts are difficult to determine. To ensure that the program achieves its intended policy objectives while minimizing potential adverse consequences for patients, healthcare delivery systems, and the broader economy, it is essential that CMS establish and maintain robust processes for the ongoing monitoring, evaluation, and public reporting of these outcomes.

The Center recognizes that research and evaluation activities are not expressly required in sections 1191 through 1198 of the Social Security Act, as added by sections 11001 and 11002 of the Inflation Reduction Act (IRA) and may be outside the scope of the draft guidance. However, we strongly encourage CMS to seek opportunities to highlight or incentivize external research and evaluation in key areas of concern to ensure the DPNP achieves its intended statutory objectives. Examples of priority areas for research and evaluation include:

- Changes in utilization management practices by Part D plans following negotiations;
- Changes in formularies that may impact patient access to therapeutic alternatives to negotiated drugs;
- Shifts in the utilization or billing of non-drug health services in place of Part B drugs;
- Increases in disparities in access or cost impacts for specific patient populations resulting from the changes listed above or shifts in pricing, including the measurement

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[6] Available at https://valueresearch.org/wp-content/uploads/2025/06/2023-IVI-Comments-to-CMS-regarding-IRA-implementatoin_FINAL.pdf and https://valueresearch.org/wp-content/uploads/2024/07/IVI-Comments-to-CMS-regarding-IRA-DPNP-2024-implementation-draft-guidance_FINAL.pdf

[7] A Blueprint for Patient-Centered Value Research (forthcoming July 2025). Center for Innovation & Value Research. https://valueresearch.org/wp-content/uploads/2025/03/2025-03-02.Blueprint-for-Patient-Centered-Value-Research_Draft-for-Comments.pdf

and monitoring of non-clinical economic impacts resulting from pricing changes or plan-level implementation.[8]

Conclusion

The Center appreciates the opportunity to comment on the draft guidance. We urge CMS to adopt the recommendations outlined in these comments and comments on previous draft guidance documents, making the DPNP more scientifically rigorous, transparent, and patient-centered. Throughout this process, we encourage CMS to ensure that evaluations of price are consistently accompanied by meaningful consideration of patient-centered value, reflecting the real-world outcomes, experiences, and priorities of patients and their families.

Thank you for the opportunity to comment. If you have any questions or would like to speak to us further about our recommendations, please contact me at rick.chapman@valueresearch.org.

Sincerely,

Rick Chapman, PhD
Chief Science Officer

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[8] Malik, E., Bright, J., Ridley, E., Cope, E., & Edmunds, M. (2023). *A research framework to understand the full range of economic impacts on patients and caregivers*. Innovation and Value Initiative & AcademyHealth.