IVI INNOVATION AND VALUE INITIATIVE

June 28, 2024

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Dr. Seshamani,

The Innovation and Value Initiative (IVI) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) on the revised draft guidance for implementation of the Medicare Drug Price Negotiation Program (DPNP) for initial price applicability year 2027 and manufacturer effectuation of the maximum fair price (MFP) in 2026 and 2027.

IVI is a 501(c)3, non-profit research organization committed to advancing the science, practice, and use of health technology assessment (HTA) in healthcare. Founded in 2017, the organization includes members from the research, patient, payer/purchaser, clinician, and innovator stakeholder communities. IVI's work emphasizes collaboration and exploration of new solutions to pursue a U.S. learning healthcare system supported by patient-centered HTA and focused on high-quality, efficient, innovative, and equitable care for all people and communities. We believe this is only possible with a fundamental shift to resource allocation, coverage, and access-related decision-making that aims to maximize value for all stakeholders—particularly patients and other covered individuals.

As described in our April 14, 2023, comments on the initial Medicare DPNP draft guidance,[1] our work is guided by our Principles for Value Assessment.[2] These principles apply not only to the narrow context of HTA but are the foundation of a patient-centered and equitable health system based on value to all stakeholders. 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, equity, and vigorous methods enhancement.

[1] Available at: https://thevalueinitiative.org/wp-content/uploads/2024/06/IVI-Comments-to-CMS-regarding-IRA-implementation_FINAL.pdf

[2] Full description of our Principles for Value Assessment in the U.S. available at: https://thevalueinitiative.org/who-we-are/value-principles/

These principles guide all our work, especially in our engagement around DPNP, health equity, and patient engagement issues. With these principles as our framework, we offer the following comments with the summary recommendation that CMS communicate publicly how input from patients, families, and caregivers was used to implement the process and drive decision-making.

IVI commends CMS for its openness to dialogue and its implementation efforts to date

We recognize that in addition to the challenge of building and implementing a complex new program under significant time constraints, CMS must balance the competing needs, concerns, and requests of diverse stakeholder groups while 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).

As in our past comments, IVI recognizes that the legislation includes specific guidelines and places limitations on the implementation of the DPNP. We commend CMS for its ongoing efforts to develop thoughtful, thorough guidance under considerable time constraints. The current draft guidance, revised for 2027 negotiations, reflects important learnings from the past year's negotiation process, CMS's commitment to continuous improvement of the negotiation process, and CMS's active efforts to incorporate the feedback provided by stakeholders, especially patients and caregivers.

IVI acknowledges and appreciates the openness of CMS and the IRA implementation staff to engage in discussions around challenging topics such as the equity implications of IRA implementation choices.

The Draft Guidance reflects important improvements over initial guidance

Changes and additions included in the draft guidance have addressed several concerns about the guidance for price applicability year 2026 and incorporate some learnings and feedback received in the first year of Medicare DPNP implementation. In particular, we commend CMS for the following revisions and additions to improve the Medicare DPNP:

Incorporation of equity as a principle and component of the DPNP

A principal concern included in IVI's comments on the initial guidance for the Medicare DPNP was a lack of consideration of health equity. This omission from the initial

guidance belied the interest expressed by CMS during interactions with IVI both prior to the initial guidance and in subsequent months. We applaud CMS for making some key changes in the draft guidance that represent significant steps toward implementing an equity-centered Medicare DPNP, especially:

- Committing (in Section 60.3.3.1) to "evaluate health outcomes for specific populations, including **through an access and equity lens;**"
- Expansion of the definition of "specific populations" to include those that may experience disparities in access to care, health outcomes, or other factors that impact health equity (in Appendix A); and
- Addition to Appendix A of a definition of "health equity."

Further comments and recommendations on this topic are described below.

Commitment to more effective and robust engagement opportunities for patients, caregivers, and other stakeholders

The draft guidance (specifically section 60.4) and supporting materials, such as the specific areas for comment in the accompanying Fact Sheet[3], demonstrate CMS's commitment to continuing to improve engagement with patients, caregivers, and other non-manufacturer stakeholders. IVI applauds CMS for recognizing the need for improvement, humility in inviting suggestions and feedback, and openness to expanding opportunities for engagement. We recognize that engagement activities represent a resource- and time-intensive addition to Medicare DPNP implementation. A robust engagement program is essential to a patient- and equity-centered DPNP.

Further comments and recommendations on this topic are described below.

Improved clarity around definitions, outcomes, and analyses

The draft guidance improves upon the previous guidance for price applicability year 2026 by providing clarification on several points, including:

- Addition of clearly stated definitions of unmet need and therapeutic advance;
- Additional information in Section 60.3.3.1 on the types of outcomes that CMS may consider; and
- Clarification in section 50.2 of the criteria by which submitted evidence will be weighed and adjudicated (e.g., study limitations, generalizability, etc.) and statement that, "in considering impact on specific populations and patients with unmet medical needs, CMS will prioritize research specifically designed to focus

[3] Available at: https://www.cms.gov/files/document/fact-sheet-medicare-drug-price-negotiation-program-ipay-2027-and-manufacturer-effectuation-mfp-2026.pdf

> on these populations over studies that include outcomes for these populations but for which these populations were not the primary focus."

Engagement is key to ensuring patient- and equity-centered implementation

In our interactions with CMS, past comments on Medicare DPNP guidance, and published recommendations for DPNP implementation, IVI has repeatedly stressed the importance of adopting an inclusive and patient-driven approach. Such an approach is essential to ensuring CMS's negotiation process and its resulting impacts on access and outcomes advance patient well-being and principles of equity.

IVI commends CMS for recognizing the shortcomings of the patient listening sessions and stakeholder engagement opportunities in the first round of negotiations. By openly inviting input on how to better engage with patients and other stakeholders, CMS is taking an important step toward improving processes in the upcoming round of 2027 negotiations. In response, IVI offers the following recommendations:

Format and frequency

The draft guidance notes a variety of potential meeting formats (listening sessions, focus groups, and others). IVI recommends that CMS not limit engagement to a single type or subset of formats, but rather outline a set of potential formats from which CMS may select the most appropriate based on topic and intended use of the information. CMS should engage with subject matter experts in academia and patient communities to develop this set of optional formats and decision guidance to assist in selecting a format for a given event.

In addition, IVI strongly recommends that CMS establish a mechanism for external stakeholders to request meetings on specific topics. IVI recognizes that CMS has a finite capacity to organize such meetings, and a well-articulated process for determining which meetings to host should be developed, including provisions for CMS-approved meetings held by external parties.

Role of engagement activities in negotiation process

Listening sessions, focus groups, and other engagement activities provide a medium for collection of patient experience information, as the draft guidance notes. These sessions should also be incorporated as a tool in the analysis and negotiation process itself.

For example, the draft guidance states at the beginning of section 60.3.3.1 that "CMS will identify outcomes to evaluate for each indication of the selected drug." Patients, caregivers, and other non-manufacturer stakeholders should be formally engaged in identifying and prioritizing both existing health disparities and the outcomes evaluated. Similarly, CMS should use stakeholder sessions, such as roundtables, to discuss prioritization of these disparities and outcomes based on patient-identified importance.

In addition, engagement activities should encompass broader questions intended to inform negotiation processes generally (not specific to a given drug or therapeutic area). For example, CMS should incorporate engagement activities to better articulate an equity approach within the DPNP. Ideally, these activities would begin before CMS receives data from manufacturers. Engagement activities themselves in addition to an advisory group, such as a standing stakeholder review committee, could also provide a mechanism for review, evaluation, and accountability currently lacking in the program.

Further steps to center equity are needed

As stated above, CMS has demonstrated interest in addressing equity-related concerns since beginning the implementation of the IRA, and IVI commends CMS for improving the draft guidance.

On December 5, 2023, IVI partnered with the Alliance for Aging Research, National Pharmaceutical Council, and Leavitt Partners, LLC, to host a half-day symposium to examine issues related to equity and engagement in implementation of the IRA by the CMS, to identify concrete, realistic, and actionable recommendations. The symposium brought together lived experience, policy and scientific expertise from various perspectives including patients and patient advocacy, quality measurement, government agencies, the biopharmaceutical industry, academia, and elsewhere.

The proceedings from this symposium[4], as previously shared with CMS, generated multiple important insights and recommendations. Above all, the discussion underscored that, while the work needed to advance equity and inclusion is complex and challenging, it is also critical that CMS demonstrate leadership in committing both philosophically and materially to a collaborative equity-centered approach to implementation, particularly in the Drug Price Negotiation Program (DPNP), with agency support for development and implementation of this process by the CMS DPNP staff. An overarching theme of the discussion with critical implications for Medicare DPNP implementation was that equity is not a "solvable problem" but rather an "ongoing goal"

[4] Available at: https://www.cms.gov/files/document/fact-sheet-medicare-drug-price-negotiation-program-ipay-2027-and-manufacturer-effectuation-mfp-2026.pdf

that CMS should continuously strive towards in all decisions made in the implementation of IRA and conduct of the DPNP.

IVI commends CMS for indicating its intention to evaluate health outcomes "through an access and equity lens." However, equity-centered implementation requires that CMS apply such a lens to the evaluation of health outcomes and the entire DPNP process itself. Furthermore, an access and equity lens should consider implications for equity across all dimensions of the Medicare DPNP, including:

- Process, especially regarding partnership-based and community engagement opportunities, inclusion of specific populations, and self-evaluation;
- Identification of disparities and equity analysis of how the process impacts existing disparities:
- Representativeness, bias, and outcomes included in evidence and analysis; and
- Impacts on access, health outcomes, financial burden, and other potential outcomes for Medicare enrollees and the broader U.S. population.

While recognizing the failure of IRA legislation to include equity as a goal or consideration, IVI strongly recommends that CMS incorporate the following as central components of the Medicare DPNP:

- Robust patient and health equity stakeholder and community engagement program that actively goes to where patients are and brings stakeholders into an ongoing dialogue with a meaningful role in DPNP operations;
- Compensation for patients and caregivers to acknowledge their time and expertise through participation in engagement activities (e.g., focus groups, interviews, and other patient-focused events);
- Transparent, accessible, and explicit communication of goals, intentions, needs, practices, and uncertainties, both forward-looking and past reporting, in multiple formats—plain language, threshold languages, infographics, video vignettes, etc.; and
- Continuous quality measurement and improvement based on process and outcomes measures, regular reflection and evaluation, incorporation of learnings into program changes, and external reporting of these efforts.

In the draft guidance, CMS has taken important initial steps toward such an approach. IVI commends CMS for taking these initial steps and recognizes that the equity-centered approach described above will require time, resources, and potential clarification to the governing legislation. In the meantime, CMS should indicate its intentions through external communications and engagements that clarify long-term goals and equity objectives. Similarly, CMS should incorporate plans for regular qualitative and, if possible, quantitative self-evaluation that includes an assessment of

Medicare DPNP implementation within the recently revised CMS Health Equity Framework[5].

In addition, IVI offers the following specific recommendations regarding the content of the draft guidance:

- Clarification of "access and equity lens"
    - Provide a provisional definition that reflects the considerations outlined in the comments above.
    - As part of discussion of potential engagement opportunities in Section 60.4, include equity-focused engagement activities (e.g., focus groups or town halls) intended to contribute to defining this term.
- Include a discussion of if/how unmet medical needs will be treated differently for specific populations in Section 60.3.

Further information on past and planned approaches is needed

While IVI appreciates the steps CMS has taken to address previous comments and provide more specificity and transparency around its "qualitative approach," a high degree of uncertainty and lack of clarity persists. Areas of concern include:

- Adjudication of evidence – especially regarding relative weighting of evidence types and sources, steps to ensure patient experience data and patient preference data are included, and measures to ensure representation and consideration of specific populations;
- Role of engagement and patient voices in DPNP implementation and operation decisions, evaluation and analysis, negotiations, and determination of Maximum Fair Price;
- Steps to specify outcomes for inclusion in analyses or other aspects of negotiations, especially concerning consideration of patient preferences, equity, and potential for bias by omission; and
- Methods to address nuance and complexity when evaluating therapies across multiple indications, particularly when affected populations or equity implications may vary across indications.

As stated in our comments on the guidance for Price Applicability Year 2026, IVI understands the need for flexibility in CMS's approach. As CMS refines this approach over the initial years of program implementation, we strongly encourage CMS to

[5] Available at: https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf

develop a detailed and well-articulated framework for this approach for inclusion in program guidance. In the meantime, however, visibility into CMS's approach is limited to observation of CMS's actions and justifications for determination of MFP in prior years' negotiations.

Publication of CMS's approach to determining MFP for the year 2026 is not expected until Spring 2025. We fully recognize that the statute clearly specifies timelines for DPNP implementation. Nonetheless, without insight into decisions made as part of this qualitative approach to date, it is important to emphasize that the ability of the public to provide constructive comments and recommendations on the draft guidance is limited. In the interim, we strongly encourage CMS to explore options for sharing information about its approach to date to bolster transparency, improve the quality and relevance of public comment, and reduce the risk of perpetuating issues with or unintended consequences of CMS's approach.

CMS has noted that the implementation of the Medicare DPNP will be iterative, with continual improvements. It is impossible to provide constructive, or even relevant, comments and suggestions without an articulated strategy or set of objectives. CMS should communicate a roadmap for DPNP implementation over the coming years, with clearly stated objectives and areas of need for insight.

We appreciate the opportunity to provide input on this important issue. Please do not hesitate to contact me or Mark Linthicum, Director of Policy, at mark.linthicum@thevalueinitiative.org for further discussion.

Sincerely,

Jason Spangler, MD, MPH, FACPM
Chief Executive Officer
Innovation and Value Initiative