IVI INNOVATION AND VALUE INITIATIVE

Policy Symposium: Ensuring Equity in Implementation of IRA Drug Price Negotiations

CONVENING PROCEEDINGS REPORT
DECEMBER 2023

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LIST OF ACRONYMS

AMCP	Academy of Managed Care Pharmacy
AHRQ	Agency for Healthcare Research and Quality
CMS	Centers for Medicare and Medicaid Services
DEI	Diversity, equity, and inclusion
DPNP	Medicare Drug Price Negotiation Program
FDA	U.S. Food and Drug Administration
IRA	Inflation Reduction Act of 2022
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
IVI	Innovation and Value Initiative
NCCN	National Comprehensive Cancer Network
NPC	National Pharmaceutical Council
PAS	Patient Affairs Staff (U.S. FDA)
PCORI	Patient-Centered Outcomes Research Institute

EXECUTIVE SUMMARY

Background and Objectives

The Innovation and Value Initiative, the Alliance for Aging Research, Leavitt Partners, LLC, and the National Pharmaceutical Council hosted an in-person public event focused on health equity, patient engagement, and related methodological and evidence issues in CMS's implementation of the Drug Price Negotiation Program (DPNP) as mandated by the Inflation Reduction Act (IRA). The half-day event brought together a range of perspectives in a series of four panel discussions with the following objectives:

- Examine implementation of the Drug Price Negotiation Program (DPNP) through a patient engagement and equity lens.
- Draw on diverse perspectives with both practical, on-the-ground experience and broader policy and scientific expertise to identify immediate and future equity implications of negotiations proceeding under current guidance and future implementation decisions.
- Generate actionable recommendations for consideration as CMS moves forward with the DPNP.

Program Overview

The four moderated discussions explored the equity implications of the DPNP:

- Equity in the DPNP Context—What Does Good Look Like?
- People, Power, and Process: Including Diverse Patient Perspectives in a Meaningful Way
- Data and Evidence: Challenges in Developing Evidence Based Methods
- Context, Consequences, and Opportunities: Concrete Recommendations for Next Steps

Key Themes

Throughout the day, speakers and participants raised common themes:

- CMS should center equity in IRA implementation, with awareness of context and constraints.
- Meaningful stakeholder and community engagement is critical, both as a process measure and as a tool to center equity in DPNP.
- Transparency, clarity, and representativeness are key considerations for data, evidence, and related methods.
- Equity-focused implementation requires continuous measurement, evaluation, and improvement.
- CMS's approach should be humble, curious, and collaborative.

Recommendations

CMS should commit to an equity-centered, transparent, and learning-focused DPNP process, with agency support for development and implementation of this process by the CMS DPNP staff, including:

- Robust patient and health equity stakeholder and community engagement program that brings stakeholders into an ongoing dialogue and with a meaningful role in DPNP operations;
- Transparency and explicit communication of goals, intentions, needs, practices, and uncertainties, both forward-looking and past reporting; 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.

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INTRODUCTION AND BACKGROUND

The passage by Congress of the Inflation Reduction Act (IRA)[1] introduced significant reforms to the Medicare program intended to reduce costs of prescription drugs to both the Medicare program and its enrollees. Implementation of the reforms mandated by the IRA—and mandated negotiations for high-cost drugs in Part D—is likely to have broad effects on patient health, healthcare access, pharmaceutical innovation, and the healthcare market, with unknown but potentially significant implications for health equity.[2] As a pillar of the Centers for Medicare and Medicaid Services (CMS) strategic plan and a stated priority of the Centers for Medicare,[3] it is essential that IRA implementation, including the Drug Price Negotiation Program (DPNP), include health equity as an objective. However, both health equity specifically and broader issues of diversity, equity, and inclusion (DEI) have been largely absent from the discourse around CMS's implementation of the IRA to date.

Figure 1. Symposium Objectives

- Examine implementation of the Drug Price Negotiation Program (DPNP) through an equity lens.

- Draw on diverse perspectives with both practical, on-the-ground experience and broader policy and scientific expertise to identify immediate and future equity implications of negotiations proceeding under current guidance and future implementation decisions.

- Generate actionable recommendations for consideration as CMS moves forward with the DPNP.

The Innovation and Value Initiative (IVI), the Alliance for Aging Research, Leavitt Partners, LLC, and the National Pharmaceutical Council (NPC) convened a half-day symposium on December 5, 2023, in Washington, D.C., "Ensuring Equity in Implementation of IRA Drug Price Negotiations." The symposium brought together policy professionals, agency staff, patient communities, and other subject-matter experts[4] to examine implementation of the IRA drug price negotiation provisions through a patient-centered equity lens and develop a set of actionable recommendations for CMS (see Figure 1).

The Summit symposium was organized into four sessions to identify cross-cutting concerns, unifying themes, and recommendations (see Figure 2). The opening discussion provided a broad orientation to equity concepts and concerns in the context of Medicare Part D and CMS's implementation of the IRA.

The three subsequent panel discussions focused on distinct but related areas, with each session building upon those preceding it. The first panel session focused on the domain of "People, Power, and Process," and the following panel focused on issues and solutions related to "Data and Evidence." The final panel session on "Context, Consequences, and Opportunities" explored broader consequences of IRA implementation, focusing on synthesizing preceding discussions and identifying specific recommendations.[5]

This report contains proceedings and recommendations from this symposium, which are intended to inform the approach, planning, and day-to-day decision-making of CMS leaders and staff in implementation of the DPNP as mandated by the IRA. In addition, this report includes related guidance for other stakeholders engaged in, or affected by, DPNP implementation.

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1   Public Law 117-169—Aug. 16, 2022. https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf
2   See Appendix 1 for definitions of key terms.
3   CMS Strategic Plan Fact Sheet. Pillar: Health Equity. https://www.cms.gov/files/document/health-equity-fact-sheet.pdf
4   See Appendix 2 for number of attendees by sector.
5   Organization of session topics was based on the main domains described in IVI's Health Equity Framework. While the DPNP is distinct from formal health technology assessment (HTA), the principles largely apply to comparative effectiveness and its use in decisions that affect coverage and access. Additional information available at: https://thevalueinitiative.org/health-equity-initiative/

Figure 2. Summary of Symposium Program

Equity in the DPNP Context—What does good look like?

This level-setting conversation drew on speakers' expertise and first-hand knowledge to explore three key questions:

- What does equity mean in the DPNP context?
- What can we learn from other contexts?
- What would an equitable DPNP look like?

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

Gary Puckrein, PhD
President & CEO
National Minority Quality Forum

Andrea Thoumi, MPP, MSc
Community Health and Equity Area Lead and Faculty Director of Health Equity Education
Duke-Margolis Center for Health Policy

People, Power, and Process

Panelists examined the current DPNP process in terms of successes, concerns, and implications for health equity and patient engagement and discussed potential steps to better advance health equity and ensure patient-centered decision-making throughout IRA implementation.

Omar A. Escontrías, DrPH, MPH (moderator)
Senior Vice President of Equity, Research and Programs
National Health Council

Michael Ward, MS
Vice President of Public Policy and Government Affairs
Alliance for Aging Research

LCDR Ashley Channels, PharmD, BCPS
Program Coordinator, Patient Affairs, Office of Clinical Policy and Programs, Office of the Commissioner
U.S. Food and Drug Administration

Tammy Boyd, JD, MPH
Vice President, Federal Relations and Strategic Alliances
American Cancer Society Cancer Action Network

Data and Evidence

This panel focused on challenges CMS faces in developing evidence-based methodology, the potential implications of these decisions for equity, and steps CMS might take to support inclusion of patient-identified outcomes, ensure equitable representation, and engage with researchers, patient groups, and other organizations to address these issues.

Rick Chapman, PhD (moderator)
Chief Science Officer
Innovation and Value Initiative

Jon Campbell, PhD, MS
Chief Science Officer
National Pharmaceutical Council

Anika Rahman
International Advocacy & Policy Director
International Foundation for Autoimmune & Autoinflammatory Arthritis

Context, Consequences, and Opportunities

As the DPNP proceeds, how should CMS and others evaluate whether it is patient-centered and equitable? What changes in law, policy, research, drug development, or elsewhere are necessary, and how should CMS navigate through issues outside of the agency's influence? This panel took up these questions and more and discussed concrete steps CMS, policymakers, and others can take.

Andrea Maresca, MPH (moderator)
Managing Director, Information Services
Health Management Associates

Josh Trent, MS
Managing Principal
Leavitt Partners, LLC

Geni Tunstall, JD
Director of Regulatory Affairs
Academy of Managed Care Pharmacy

Bryan O. Buckley, DrPH, MPH, MBA
Director, Health Equity Initiatives
National Committee for Quality Assurance

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KEY THEMES

From the outset, participants agreed that questions around equity in any context, and particularly the DPNP and IRA implementation processes, are challenging but critical endeavors. Several of the most prominent themes are described below.

CMS should center equity in IRA implementation, with awareness of context and constraints.

Discussants agreed that equity is not a "solvable problem" but rather an "ongoing goal" that CMS should continuously strive towards. Decisions made in the implementation of IRA and conduct of the DPNP should use equity as a compass, but with a realistic understanding of its ability to do so considering CMS's mandate, its role as payer rather than provider, and that IRA implementation is governed by legislation that does not include equity as a goal or consideration.

Participants often underscored that process— not only outcomes—matters, pointing out that CMS's approach to implementation could have significant impacts on public trust in the Medicare program. Most importantly, the discussions stressed the importance of adopting a learning attitude entailing candor about limitations and learning points, actively seeking out feedback and learnings from other agencies and diverse Medicare patients and their caregivers and looking to fields like quality measurement and improvement for best practices.

Figure 3. FDA as an Example of Equity-Focused Agency Engagement

Several attributes of the FDA Patient Affairs program were highlighted as particularly relevant.

- Focus on bi-directional communication and collaboration with patient communities.
- Emphasis on diverse representation, inclusion, and elevating the voices of smaller communities.
- Agency commitment to engagement, with dedicated staff and resources.
- Improvement of program over time, especially in response to "equity hurdles."
- Program includes two types of meetings, with FDA resources provided to organize both:
  - FDA-initiated and -organized
  - Partner-brought meetings
- Engagement activities and stakeholder input incorporated into agency operations with multiple purposes including:
  - Informing specific product reviews
  - Shaping FDA guidance
  - Identifying and interpreting key patient-important and patient-reported outcomes

Meaningful engagement is critical, both as a process measure and as a tool to center equity in DPNP.

Program participants emphasized that meaningful, ongoing, and dialogue-focused engagement with diverse stakeholder—particularly patient, caregiver, and advocate—communities is the foundation for an equitable and equity-focused DPNP. As one speaker noted, "patient-engagement is an ongoing, two-way conversation" that allows all parties to learn from the others, adjust implementation to meet community needs and address unexpected consequences, and build trust.

Reflecting on the current DPNP process (to date), however, participants voiced concern that opportunities for engagement and patient and caregiver input were limited to submission of patient experience data and participation in listening sessions. Discussing the listening sessions held in November 2023, participants highlighted several specific concerns about potential equity implications, including:

- Listening sessions were "one-directional" with no feedback or questions from CMS staff or dialogue with speakers.[6]
- There was a lack of communication and transparency around the goals of patient listening sessions, how stakeholders can or should engage with CMS, how listening session input would be used, process for selecting speakers for sessions, and what follow-up would be provided.
- Holding one listening session per selected drug may provide unequal opportunities for patient and caregiver input when multiple drugs in the same therapeutic area are selected.
- Multiple speakers and participants expressed concerns around accessibility and accommodations, including: 3-minute time allowances and lack of scheduling flexibility (for a surgeon delayed by complications in surgery or patient speakers with conditions affecting ability to speak); input only accepted in form of live, public speaking; and lack of translation to/from languages to meet the needs of communities with another preferred language.

Figure 4. Specific Strategies to Increase Equity and Inclusivity Employed by FDA Patient Affairs

Lowering Barriers and Facilitating Bi-Directional Communication.

- Plain-language publications
- Materials and meetings are translated into multiple languages by native speakers
- Any individual or organization may request to have a meeting organized
- FDA provides resources needed to organize meetings
- All meetings are virtual or hybrid to remove barriers and burdens associated with travel for in-person meetings
- Collaboration with requesting partners on agenda and meeting organization
- Dedicated Patient Affairs Staff (PAS) created as a door to the FDA for those unsure where to start
    - Help direct meeting requestors towards the right meeting type for their goals
    - Resource for patients/caregivers/advocates to help facilitate communication and enhance participation
    - Includes team members specializing in health literacy

Promoting Diversity and Inclusion

- PAS encourages requestors to:
    - Work with all patient organizations in the same health condition/disease space
    - Showcase diverse patient voices during their meeting
- For FDA-requested listening sessions, PAS works with the requesting FDA division to determine what criteria they are looking for in patients, and then works to gather the most diverse group of potential participants as possible
    - Utilize outside partners such as foundations, patient/advocacy groups, and others to help attract a diverse applicant pool

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6   Patterson, J. et al. (2023) Three Takeaways from CMS's Patient-Focused Listening Sessions: Toward Improved Patient Engagement. *National Pharmaceutical Council*. https://www.npcnow.org/resources/three-takeaways-cmss-patient-focused-listening-sessions-toward-improved-patient

Participants stressed that meaningful engagement is both possible and essential in the IRA implementation process, however, and offered multiple examples of effective and equitable engagement approaches employed by other agencies and organizations. The Patient Affairs program at FDA was cited most frequently as a model for patient and caregiver engagement and, as a relatively new focus within FDA, a potential source of "lessons learned" (see Figures 3 and 4). Other examples included organizations operating at the national level (e.g., the Patient-Centered Outcomes Research Institute) and the state- and community-level organizations such as LATIN-19[7] in North Carolina. Key characteristics of these efforts that position them to advance equity included the initiating organization's focus on stakeholder or community engagement as a priority instead of a requirement; efforts to remove access barriers and increase inclusion of underrepresented populations; two-directional communication; and involvement of stakeholders in initiating meetings, developing agendas, and identifying and prioritizing next steps. Participants placed particular emphasis on the importance of "going into" communities to bring underrepresented perspectives into the process, rather than expecting stakeholder and other key experts to initiate this engagement.

Transparency, clarity, and representativeness are key considerations for data, evidence, and related methods.

Participants identified the need for clear, detailed, and transparent communication as a key requirement for equity-centered DPNP implementation. In engagement with patient and caregiver communities, lack of trust may deter many groups or individuals from contributing their voices or sharing information, and clear communication of goals, use of information, and expectations for (and potential burden of) participation is required to build and preserve trust. For example, one participant described how some patients interested in speaking at the recent patient listening sessions declined because this information was not available without first sharing their email addresses. Because stakeholder communities' trust and willingness to engage may be associated with characteristics like income or race, this has important implications for equity and engagement with certain communities.

Clarity and transparency also affect the representativeness and relevance of the information provided to CMS, especially in the context of data and evidence collection, submission, adjudication, analysis, and use in negotiations. Evidence collection and submission are time consuming and resource intensive, and lack of clear guidelines for needed/requested data and how they would be used risks wasted effort on irrelevant evidence, with potentially disproportionate burden on patient groups and less-resourced communities.

In addition, equity in the context of data and evidence entails having the right data on the right outcomes—representative of diverse communities, unbiased, and capturing the outcomes that are important to patients/caregivers. Participants emphasized that signaling in advance the data collection needs and key outcomes is critical, as is communicating how they will be used. Patient engagement provides a valuable approach to identify outcomes of importance; FDA's work in patient engagement and patient-focused drug development are excellent examples of this (Figure 3). In addition to identifying the key outcomes for patients, discussants pointed to the need to include key indicators like social determinants of health and consider data source options including qualitative data from patient and caregiver listening sessions and real-world evidence.

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7   More information on LATIN-19 is available at. www.latin19.org. See also:
   •   Thoumi, A., et al. (2023). Promoting Latinx health equity through community-engaged policy and practice reforms in North Carolina. Frontiers in Public Health. https://www.frontiersin.org/articles/10.3389/fpubh.2023.1227853/full
   •   Maradiaga Panayotti, G.M., et al. (2022). LATIN-19: A Grassroots Coalition to Mitigate the Effect of COVID-19 on the Latinx Community in North Carolina. Progress in Community Health Partnerships: Research, Education, and Action 16(2), 33-38. https://doi.org/10.1353/cpr.2022.0036
   •   Thoumi, A., et al. (2021). Bridging The Health Equity Gap: Strategies To Create An Equitable Health System For Latinx Communities. Health Affairs Forefront. https://www.healthaffairs.org/content/forefront/bridging-health-equity-gap-strategies-create-equitable-health-system-latinx-communities

Discussion frequently pointed to risks to equity posed by lack of representativeness of data, methods used to adjudicate and weight evidence, and the selection of outcomes for inclusion in comparative effectiveness analysis. Transparency and detailed description of the methodologies used by DPNP analysts—both pre- and post-hoc—the limitations of these methods, and revisions to future guidance are essential to ensuring ongoing improvement and increased equity in the DPNP. Participants suggested that CMS would ideally develop and publish detailed best practices and evidence standards that include equity as a priority, noting that CMS has an opportunity to lead the field in this effort but can begin by looking to standards developed by organizations such as AMCP, FDA, IVI, ISPOR, NCCN, NPC, PCORI, and others.

Equity-focused implementation requires continuous measurement, evaluation, and improvement.

Throughout the day's proceedings, panelists spoke about the need for continuous evaluation and improvement of implementation. Proposed approaches to improve internal CMS processes included:

- Establish a mechanism to identify potential failures in the DPNP process, their possible impacts, and responses.
- Apply the VIBE framework for Health Equity.[8]
- Identify learning moments to ask, "What are we missing?"

Robust data collection on impacts of the DPNP and broader IRA implementation was identified as highly important, including impacts on Medicare enrollees and their families, impacts on social determinants of health, and changes in utilization management, different communities' access to therapies (especially related to rare disease), and impacts on private insurance markets and prescriber behavior.

Participants also stressed that engagement with communities, with an ongoing and open dialogue, is critical to evaluation and improvement of the DPNP process. As one speaker noted, CMS will not know the impacts of implementation on communities without talking to them. Dialogue with communities helps to clarify program goals and provides insights into how best to adjust to ensure goals are being met.

Panelists pointed to learnings from the field of quality measures and quality improvement as being relevant. One meeting attendant asked, "How will we know if DPNP processes are equitable?" Participants pointed out that in the short term, good process measures exist, including:

- Standardized data collection
- Inventorying who is included in engagement activities and decision-making
- Steps being taken to make the process accessible

However, participants emphasized that long-term outcomes measures are more important. In addition to social drivers of health disparities, participants suggested that CMS should consider measures like ease of access to therapeutic alternatives. Broader and downstream consequences of implementation were identified as important to measure and track. The most heavily emphasized of these were changes in use of utilization management and impacts on patient outcomes; interactions with other aspects of the IRA; and changes in drug introductions, launch prices, expansion of drug indications, and orphan designations.

CMS's approach should be humble, curious, and collaborative.

The entire day's proceedings pointed to the need for CMS to embrace a philosophical approach to IRA and DPNP implementation rooted in humility, curiosity, and collaboration. These attributes are relevant to all aspects of implementation activities, both internally in planning and decision-making and externally in communication and engagement with stakeholders and the public. The discussion emphasized the need for candor about limitations, uncertainties, and failures; openness to recommendations, new ideas, and change; and prioritization of collaboration and engagement.

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8   Tasha Souza and Jeremy Harper. Decision Making for Equity: Applying the VIBE Framework for More Equitable Outcomes. Faculty Focus. Available at: https://www.facultyfocus.com/articles/equality-inclusion-and-diversity/decision-making-for-equity-applying-the-vibe-framework-for-more-equitable-outcomes/

Participants stressed the importance of looking to other agencies for examples and best practices. While the Patient Affairs program at FDA was cited as a particularly relevant example (Figure 3), participants also cited the Agency for Healthcare Research and Quality (AHRQ), the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), and the Substance Abuse and Mental Health Services Administration (SAMHSA) as potential sources of insight within government. Furthermore, participants pointed to external private organizations successfully doing good quality improvement, as well as looking internally for resources and examples within CMS. Collaboration within CMS and across organizations was also emphasized.

RECOMMENDATIONS

The discussions amongst expert panel speakers and attendees overwhelmingly point to an important role—and opportunity—for CMS to lead in health equity through IRA implementation and, more specifically, the DPNP. Doing so requires that the internal CMS DPNP team, broader IRA implementation staff, and CMS as an agency embrace equity as a central guiding principle.

Principal Recommendation

CMS should commit to an equity-centered, transparent, learning-focused DPNP process, with agency support for development and implementation of this process by the CMS DPNP staff. This process should include:

- Robust patient and health equity stakeholder engagement program that brings stakeholders into an ongoing dialogue and with a meaningful role in DPNP operations;
- Transparency and explicit communication of goals, intentions, needs, practices, and uncertainties, both forward-looking and past-reporting; 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.

Within each of these areas, we outline specific recommendations below.

Recommended Action Steps

Recommendation #1: Robust stakeholder engagement program that brings stakeholders into an ongoing dialogue and with a meaningful role in DPNP operations.

Communicate intention to develop engagement processes as part of DPNP and hold town halls for input and guidance.
Early and vigorous outreach is essential to ensure frequently underrepresented and hard-to-reach communities are aware and included from the outset. As a first step, CMS should publicly announce plans to develop a stakeholder engagement program as part of IRA implementation efforts, including opportunities for early input (e.g., town halls, public comment via website, etc.), and initiate outreach and communications to raise awareness and widely encourage participation of diverse communities. These efforts should include both traditional communications activities (e.g., publications in news media, social media campaigns, etc.) and direct outreach to/through stakeholder organizations like the National Health Council, local community organizations, hospital/health systems, Community Health Centers, and other "on the ground" entities.

Seek guidance and best practices from other agencies.
Contact patient affairs and engagement teams at other agencies, especially within the patient affairs office at FDA. Request support and guidance in developing and revising plan for engagement program; specifically, request access to external resources developed to support interested stakeholders and internal resources (e.g., best practices, how-to-guides, staff training materials, etc.) and adapt for DPNP use with supplying agency guidance.

Develop draft plans for engagement program.
Draft plan should include consideration of:

- Resource needs, including dedicated staff time, IT resources, and new hires
- Communication strategies for program launch, guidance for parties interested in engaging with CMS, reporting back from meetings, and communication of input to other DPNP team members
- Potential meeting types and roles in DPNP process, including:

  - Ongoing engagement with stakeholders to guide DPNP operation and guidance development
  - Patient advisory groups for specific therapeutic areas subject to negotiations
  - Listening sessions or meetings to clarify key outcomes or collect evidence

- Formal processes within DPNP operations, planning, and decision-making (including guidance development, drug selection, outcomes for comparative effectiveness and selection of therapeutic alternatives, identification of disparities and impacts on specific populations, and evaluation of DPNP)
- Best practices and learnings drawn from other organizations and how they apply to DPNP context, especially in support of constructive two-directional communication

Initiate engagement activities immediately to guide program development.
Stakeholder input should be a central element of program design from the outset. It should also inform efforts to center equity in IRA implementation in general. CMS should host listening sessions and stakeholder work groups focused on diversity, equity, and inclusion to gather feedback, define terms, identify opportunities/concerns, and get input on potential solutions.

Take proactive measures to increase accessibility and facilitate engagement.
Seek out and identify "equity hurdles" and take steps to facilitate engagement and input, including:

- Request feedback on different dimensions of accessibility (e.g., ADA compliance, language equity, digital equity, etc.) and collaborate with stakeholders to find solutions
- Provide all forms, instructions, and other materials in multiple languages, translated by native or bilingual speakers
- Provide multiple ways to provide input (in addition to speaking in live meetings, accept written and prerecorded statements) and accommodate input in multiple languages
- Make efforts to accommodate the challenges and constraints experienced by patients, caregivers, clinicians, and others (e.g., if unable to join a meeting at a specified time because of need to provide care to family member)
- Develop training and support materials in plain language to guide patients and other stakeholders in engagement, including joining working groups, submitting comments, and collecting and submitting data or evidence

Hire or reassign staff to support engagement activity as a central component of DPNP operations.
Establish dedicated permanent staff to develop and roll out engagement program, manage ongoing engagement activities, and liaise with broader DPNP team. Because engagement requires specialized skills, staff with experience and expertise in engagement should be hired or assigned, along with support staff with sufficient resources and protected time to support engagement activities.

Recommendation #2: Commit to maximum transparency in all aspects of IRA and DPNP implementation.

Communicate with clarity and transparency the purposes and roles of stakeholder engagement.
Wherever possible, DPNP program guidance should explicitly describe opportunities for patient and other stakeholders to contribute to DPNP processes, the role they will have in decision-making or program execution, and the type of input required. In conducting engagement activities within an engagement program, all meetings or work groups should have clearly articulated goals, and CMS should explicitly state what type of input is needed and its intended use. In reports and self-assessments, the use of past input should be clearly described.

Provide clear, explicit, and detailed documentation of evidence needs and planned methods for comparative effectiveness analyses.
As a high priority, CMS should provide advance direction to the greatest possible extent to guide and support collection and submission of evidence for therapeutic comparison and negotiation processes.[9] Specifically, CMS should specify the outcomes to be used in the comparative analyses, the methods to be used in adjudicating and weighting data, analytic approaches, and the role of these analyses in negotiations. This step is essential because: it ensures CMS receives relevant outcomes data; it provides transparency about the weighting of data, representativeness of included evidence, and any resulting equity concerns; it signals to researchers and patient groups what evidence may need to be collected at an early stage; and it ensures research effort and resources are being directed to relevant evidence development.

Identify and describe evidence needs, priority outcomes, and limitations.
CMS should identify evidence needed to conduct equitable, patient-focused analyses to signal to the research community and patient groups what data may be needed in future. Major evidence gaps should be identified, and in all negotiations, CMS should describe how these evidence gaps may have impacted comparative analyses and what steps were taken to account for this, if any.

Develop and publish best practices for equity-focused outcomes collection and analysis.
Collaborate with or support work of organizations such as ISPOR, NCCN, AMCP, and others to develop best practices as a framework for the field and to guide evidence development. As part of this effort, consider defining a set of core patient- and equity-focused outcome measures for use across disease or therapeutic area.[10]

Recommendation #3: Implement a learning-focused operational approach focused on continuous evaluation and improvement with equity as a guiding principle.

Explicitly commit to equity as the "compass" guiding IRA implementation.
CMS should recognize and reaffirm its commitment to health equity as a pillar of its strategic plan with a public commitment to prioritizing equity as a guiding principle for IRA implementation and DPNP operations. To foster public trust and create accountability, CMS should establish an annual calendar for review and revision of program guidance that includes evaluation of progress toward equity goals, multiple opportunities for engagement and public input, and transparent evaluation of opportunities and challenges for current- and future-year revisions.

Cultivate internal culture and practices of a learning organization.
Make continuous equity-centered evaluation and quality improvement a core part of program leadership and operations, including such steps as:

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9   O'Brien, J. et al. (2023). Section 50 of the Inflation Reduction Act Drug Price Negotiation Program: Considerations for the Centers for Medicare and Medicaid Services, Manufacturers, and the Health Economics and Outcomes Research Community. Value in Health. https://www.ispor.org/publications/journals/value-in-health/abstract/Volume-26--Issue-12/Section-50-of-the-Inflation-Reduction-Act-Drug-Price-Negotiation-Program--Considerations-for-the-Centers-for-Medicare--Medicaid-Services--Manufacturers--and-the-Health-Economics-and-Outcomes-Research-Community
10   See related work by National Health Council.

- Regularly conduct equity-focused self-assessments with agency teams and with stakeholders, using a specific framework[11] to facilitate evaluation of progress and potential challenges over time;
- Ongoing assessment, documentation, and communication of limitations, uncertainties, and evidence gaps that pose obstacles to equity-focused implementations; and
- Emphasis on forthright and transparent communication of limitations, needs, and opportunities.

Identify and collect data on relevant health equity and DEI quality measures.
Work with external experts[12] and internal agency resources to identify and define quality measures to guide equity-centered DPNP operation and improvements. Both process and outcome measures should be used, recognizing that in the short term only process measures may be available[13] while standardized data collection on outcome measures is implemented. Broader impacts of IRA implementation should be considered, as well (e.g., changes in use of utilization engagement by Part D plans).

Use external engagement to guide internal learning and program improvement.
Seek external insights and equity-focused program assessments, invite public dialogue, and transparently communicate learnings, limitations, and areas for improvement. For example, CMS should:

- Seek feedback and guidance from diverse stakeholders through engagement program;
- Invite written evaluations by external stakeholders and experts;
- Publish regular reports detailing self-evaluation and future steps (CMMI self-assessments published in *Health Affairs Forefront* provide a potential model); and
- Actively seek guidance from experienced teams at FDA and elsewhere and utilize lessons learned and best practices to develop patient engagement program with DPNP.

CONCLUSION

As a public agency and the largest insurer in the United States, the steps taken by CMS in implementing the IRA, especially the DPNP, stand to set a precedent for the private markets and healthcare decision-making for years to come. In line with CMS's strategic plan and specific goals, it is imperative that equity in process and health equity as a program objective be prioritized. We strongly encourage CMS as an agency, and implementation teams individually, to take the action steps outlined above.

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11   Examples of frameworks for self-evaluation include VIBE Framework and failure-modes effects analysis
12   This should include experts from a range of fields and backgrounds, including organizational DEI programs and healthcare quality. For example, National Coalition for Quality Assurance (NCQA) and others are developing quality measures and approaches to health equity-centered quality improvement that may be particularly relevant.
13   These process measures might include:
- Regular and consistent self-assessment using specified frameworks
- Frequency of equity-focused engagement meetings
- Whether standardized data is being collected on identified outcome measures

IVI ✳ INNOVATION AND VALUE INITIATIVE

APPENDIX 1: DEFINITION OF TERMS

Diversity, Equity, and Inclusion (DEI)
The idea that all people should have equal rights and treatment and be welcomed and included, so that they do not experience any disadvantage because of belonging to a particular group, and that each person should be given the same opportunities as others according to their needs.[14]

Diversity
Socially, it refers to the wide range of identities. A broad view includes race, ethnicity, gender, age, national origin, religion, disability, sexual orientation, socioeconomic status, education, marital status, language, veteran status, physical appearance, etc. It also involves different ideas, perspectives, and values.[15]

Equity
The fair treatment, access, opportunity, and advancement for all people, while at the same time striving to identify and eliminate barriers that have prevented the full participation of some groups. The principle of equity acknowledges that there are historically underserved and underrepresented populations and that fairness regarding these unbalanced conditions is needed to assist in the provision of adequate opportunities to all groups.[15]

Health Equity
Health equity means that everyone has a fair and just opportunity to be as healthy as possible. This requires removing obstacles to health, such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and healthcare.[16]

The attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[17]

Inclusion
Providing equal opportunity to all people to fully engage themselves in creating an environment and a cultural attitude whereby everyone and every group feels accepted, has value, and is supported by a foundation based on trust and mutual respect.[18]

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14   *Cambridge English Dictionary*. https://dictionary.cambridge.org/dictionary/english/dei
15   *University of Washington College of the Environment. (2020). Diversity, Equity, and Inclusion Glossary. Tools and Additional Resources*. https://environ-ment.uw.edu/about/diversity-equity-inclusion/tools-and-additional-resources/glossary-dei-concepts/
16   *Robert Wood Johnson Foundation. What Is Health Equity?* https://www.rwjf.org/en/insights/our-research/2017/05/what-is-health-equity-.html
17   *CMS Framework for Health Equity 2022-2032*. https://www.cms.gov/files/document/cms-framework-health-equity-ad.pdf
18   Wright J. (2020, December 6). *The Language of Inclusion, 3rd edition. James Wants You to Know.*

APPENDIX 2: NUMBER OF SYMPOSIUM ATTENDEES BY SECTOR

SECTOR	ATTENDEES
Biopharmaceutical Industry	14
Communications	2
Consulting	6
Federal Agency	4
Patient Advocacy	13
Professional Association	1
Quality	3
Research	16
Trade Association	7
Unknown	1
TOTAL ATTENDEES	**67**

The Innovation and Value Initiative (IVI) is a 501(c) (3) tax-exempt non-profit research organization dedicated to advancing the science and improving the practice of health technology assessment through development of novel methods and the creation and application of enhanced health technology assessment models to support local decision-making needs in healthcare.

The Alliance for Aging Research is the leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care. The Alliance strives for a culture that embraces healthy aging as a greater good and values science and investments to advance dignity, independence, and equity.

Leavitt Partners, an HMA Company, helps clients thrive at the intersection of health care and the federal government. We partner with health care and human services organizations to understand and influence the policy, political, stakeholder, and other dynamics impacting health care. Our team is driven to use our decades of government and private-sector experience to make health care more accessible, effective, equitable, and sustainable.

The National Pharmaceutical Council (NPC) is a health policy research organization dedicated to the advancement of good evidence and science, and to fostering an environment in the United States that supports medical innovation. Founded in 1953 and supported by the nation's major research-based pharmaceutical companies, NPC focuses on research development, information dissemination, and education on the critical issues of evidence, innovation, and the value of medicines for patients.