

Recommendations for Enhancing CMS' Patient Engagement Strategies

Executive Summary

For over a decade, the Partnership to Improve Patient Care (PIPC) has championed centering health care on patients and people with disabilities. In this literature review, we offer the Centers for Medicare & Medicaid Services (CMS) recommendations to create a systematic engagement process that goes beyond written comment periods and ad hoc listening sessions. Drawing on robust frameworks from leading organizations including National Health Council (NHC), the Patient-Centered Outcomes Research Institute (PCORI), the PATIENTS Program at the University of Maryland, the Innovation and Value Initiative (IVI), and AcademyHealth, our recommendations prioritize authentically involving patients and people with disabilities in agency decisions. By synthesizing insights from these frameworks, PIPC advocates best practices to foster meaningful dialogue with patients, caregivers, and people with disabilities across CMS. The insights from their lived experience will allow CMS to advance policies and practices improving health care value and patient outcomes.

Our recommendations are as follows:

- CMS should develop a formalized process to ensure **continuous, robust engagement** of patients and people with disabilities at multiple levels.
- Using patient insights, CMS should **clearly communicate how it intends to use the input it receives**, and how that input is reflected in the final negotiated prices.
- CMS should solicit input from **diverse communities** to ensure representation of the diversity of the patients and communities affected by the topic.
- CMS should ensure that opportunities for patient engagement are **accessible**.
- To gauge both successes and challenges, CMS should establish a structured process for **continuous review and assessment** of its engagement strategy.
- CMS should avoid **one-size fits all value metrics**.

PIPC Recommendations for Enhancing CMS' Patient Engagement Strategies

PIPC's recommendations for enhancing CMS' patient engagement strategies are grounded in the expertise of organizations dedicated to improving health care value through meaningful engagement with patients and individuals with disabilities. These organizations have developed substantial recommendations to foster and guide patient engagement across the health care sector. Specifically, NHC, PCORI, the PATIENTS Program, IVI, and AcademyHealth have each crafted comprehensive frameworks for patient engagement, emphasizing the crucial role of meaningful and authentic patient and caregiver engagement in research processes.

In response to CMS' 2023 listening sessions on the Medicare Drug Price Negotiation Program (MDPNP), NHC convened a roundtable discussion to provide a platform for the patient community to share their experience engaging with the agency. Stakeholders outlined valuable insights gleaned from these sessions, which can contribute to shaping CMS' broader patient engagement strategies. The PATIENTS Program at the University of Maryland School of Pharmacy adopted a similar approach by hosting a Town Hall, bringing together stakeholders to gather insights and recommendations. Their aim was to ensure that patient perspectives are being represented in the agency's decision-making. PIPC's recommendations integrate the key findings, themes, and subsequent recommendations derived from both NHC's and the PATIENT Program's reports on CMS' engagement strategy.

Furthermore, we leveraged the PCORI-developed Foundational Expectations for Partnerships and IVI's Economic Impacts Framework to inform our recommendations. PCORI's six expectations serve as a framework to guide meaningful, effective, and sustainable engagement to advance patient-centered comparative clinical effectiveness research (CER). Meanwhile, IVI's framework, along with the principles used to develop it, encourages partnerships between patients, caregivers, and researchers to broaden the understanding and measurement of the six main economic impacts for patients.

By extracting key elements from these frameworks, PIPC identifies best practices CMS should adopt to enhance its patient engagement strategies, reflected in our recommendations.

CMS should work with an advisory group of experts from organizations representing people with chronic conditions and disabilities to develop a formalized process to ensure continuous, robust engagement of patients and people with disabilities at multiple levels.

There is broad consensus among policymakers and leaders in the field of patient-centered outcomes research that robust engagement of people with lived experience is crucial. As part of NHC's vision for improving CMS' patient engagement over the next five years, one of three key improvements proposed is inclusion of patient perspectives at every stage of the decision-making process. To achieve this objective, both NHC and the PATIENTS Program urge CMS to establish partnerships with the patient community and formalize a process to create multiple touchpoints with people experiencing the disease or illness being studied. This aligns with PCORI's foundational expectations for partnerships, which emphasizes the importance of initiating touchpoints early, even during planning stages of a study.

Additionally, IVI highlights that continuous partnerships provide valuable context from individuals' lived experiences to shape research priorities and NHC recommends CMS develop methods for incorporating this patient experience data into its program implementation. The experts participating in the advisory group should include those with experience engaging patients and people with disabilities throughout the life cycle of chronic conditions and

disabilities to elicit information about the range of burdens and outcomes that matter most to them, as well as the differences among subpopulations.

***Recommendation:** Based on this strong consensus and alignment of goals, PIPC recommends that CMS develop a formalized engagement process in consultation with engaged partners in the patient and disability communities that have expertise engaging people with lived experience related to their experiences with treatment. This process should not only ensure that the agency is actively engaging early and often with patient stakeholders but also guarantee ongoing engagement, fostering sustainable partnerships and building trustworthy relationships for future endeavors.*

Using patient insights, CMS should clearly communicate how it intends to use the input it receives, and how that input is reflected in the final negotiated prices.

Although CMS has asked stakeholders to go through the intensive process of submitting data pertaining to selected drugs, and has made listening sessions available to them, CMS has not explained how input will be used by CMS or will inform CMS' eventual conclusions. While the process for obtaining this information is critical, equally important is how it is being used.

This issue was highlighted during the NHC's roundtable, where numerous stakeholders expressed feeling underprepared by CMS for the 2023 listening sessions, which limited their ability to meaningfully participate. They suggested that CMS could have better communicated the purpose of the information it is seeking, and how it is being used in determining prices for selected drugs. Based on this feedback, NHC recommends CMS enhance its clarity and communication about the intent of its listening sessions — a recommendation that we would apply more broadly to the agency's holistic engagement.

Similarly, the PATIENTS Program's Town Hall echoed these concerns, leading to their recommendation for CMS to provide more information to the patient community throughout the process. They emphasize trust-building through transparency, advocating that patients should understand the agency's decision-making processes and how their input is utilized. They specifically recommend the agency develop a process to share how stakeholder feedback guides decision-making. Patients and people with disabilities, as well as the organizations representing people with the chronic conditions and disabilities being reviewed, will dedicate the time and resources to being engaged partners if they know how their input makes a meaningful difference.

***Recommendation:** PIPC encourages a cyclical approach, wherein patient engagement helps CMS communicate how it intends to use the information submitted by stakeholders on selected drugs and therapeutic alternatives. It is critical that this information is communicated to stakeholders to ensure they are prepared to provide appropriate feedback at listening sessions and have*

advance notice to gather and submit useful information throughout the process. CMS should be very explicit and transparent about the information it is seeking from patients and people with disabilities and how it will influence decisions.

CMS should solicit input from diverse communities to ensure representation of the diversity of the patients and communities affected by the topic.

The CMS Framework for Health Equity seeks to further advance health equity, expand coverage, and improve health outcomes. Additionally, the Inflation Reduction Act requires consideration of the differences among subpopulations. Therefore, it is crucial for the agency to formalize an engagement process that prioritizes feedback from diverse communities.

For example, PCORI places significant emphasis on the importance of diversity in patient engagement, particularly ensuring that research partnerships reflect diverse patients and communities affected by the topic. They explain diversity is essential to adequately address the needs of the targeted population, especially those with perspectives historically excluded from research.

NHC's roundtable on CMS' MDPNP listening sessions highlighted concerns about the lack of racial and ethnic diversity among speakers and the inadequate accommodations for speakers with disabilities. To enhance the diversity of future patient engagement endeavors, NHC recommends that CMS collaborate with the Office of Minority Health and engage with minority-led patient advocacy groups to promote broader participant diversity.

Recommendation: PIPC concurs with the necessity of ensuring that health care research represents the affected population and encourages CMS to take a proactive approach in including diverse perspectives in patient engagement efforts. In addition to engaging the Office of Minority Health and minority-led patient advocacy groups, proactive engagement with PCORI and the National Institute on Minority Health and Health Disparities (NIMHD) may be useful to identify research priorities that capture diverse perspectives.

CMS should ensure that opportunities for patient engagement are accessible.

IVI and PCORI emphasize the significance of allocating dedicated funds and resources to support and compensate patient engagement. We concur with this perspective and recommend CMS take responsibility for ensuring the accessibility of their patient engagement opportunities. PIPC has echoed these sentiments, urging CMS to allocate resources such as financial assistance, accessible materials, disability-friendly meeting arrangements, and extended input and comment periods.

The PATIENTS Program echoes PIPC's call for accessible materials, emphasizing the use of plain language and health literacy principles to ensure patient understanding and inclusivity. They also advocate for diverse engagement approaches, recognizing that online-only methods may not be accessible to everyone. Notably, NHC recommends that Congress provide this support, along with funding and oversight, to strengthen CMS' engagement efforts.

Additionally, NHC recommends that CMS enhance its own accessibility, which PIPC concurs with. Communication with executive branch agencies can often be challenging due to bureaucracy and the need for institutional knowledge to communicate effectively. Streamlining the process for initiating dialogue, such as by creating an ombudsman or a clearly identified point of contact, is essential for effective engagement.

Recommendation: CMS should create an ombudsman for engagement of stakeholders from the patient and disability communities, dedicate funds and resources to support and compensate patient engagement, and ensure accessibility through use of plain language materials and by providing opportunities for engagement through written comments, in-person meetings and online events. We call attention to the recent regulations from the U.S. Department of Justice governing digital accessibility for people with disabilities and urge CMS' focus on compliance.

To gauge both successes and challenges, CMS should establish a structured process for continuous review and assessment of its stakeholder engagement strategy.

PCORI's final expectation for patient engagement underscores the importance of gathering input and feedback throughout projects to pinpoint areas of success and areas for improvement, enabling adjustments in future engagement strategies. PCORI emphasizes that continuous learning is essential for enhancing engagement strategies, allowing researchers to assess whether engagement is effective, equitable, and as intended. The PATIENTS Program echoes PCORI's expectation, advocating for a third-party evaluation of patient and stakeholder engagement to ensure transparency and accountability. Similarly, IVI advocates for integration of health equity throughout research initiatives, ensuring equitable design and implementation.

Recommendation: CMS should commit to continuous learning, refining its patient engagement strategy and promoting health equity as part of a structured assessment of what works and what does not work, in collaboration with engaged patients and people with disabilities.

CMS should avoid one-size-fits-all value metrics.

IVI and AcademyHealth partnered with stakeholders to develop an Economic Impacts Framework, intended to guide researchers in comprehensively assessing economic impacts on patients and caregivers throughout research processes. This framework identifies six main areas of economic impact: (1) direct medical costs; (2) non-clinical health care costs; (3)

caregiver and family impacts; (4) social impacts; (5) ability to work; and (6) education and job impacts. IVI underscores that the patient or caregiver occupies a central role in this framework, with patient engagement being vital for a thorough understanding of research-related economic impacts on individuals. The PATIENTS Program draws a similar theme, noting that CMS must be open to listening to patients to understand their pain points, which may include things like direct out of pocket costs.

PIPC concurs with the importance of CMS' patient engagement efforts to grasp the full economic and clinical impacts of disease on beneficiaries and cautions CMS from relying on cost-effectiveness analysis in its process. These studies do not comprehensively capture the full benefits of treatment, relying largely on one-size-fits-all, and often discriminatory, metrics like the Quality-Adjusted Life Year (QALY) or Equal Value Life Year Gained (evLYG).

***Recommendation:** PIPC urges CMS to avoid use of one-size-fits-all value metrics, like the QALY or evLYG, as part of its decision-making, consistent with current Medicare law and regulations governing nondiscrimination. CMS should also identify and be transparent about the types and sources of research, data, and assessments considered in its decision-making process. In addition, CMS should ensure it and other entities are exercising adequate oversight over organizations such as Pharmacy and Therapeutics Committees in Part D and state-affiliated organizations such as Medicaid managed care organizations and Prescription Drug Affordability Boards to ensure their decisions about reimbursement and coverage do not rely on data from studies relying on one-size fits all metrics, like the QALY or evLYG.*

Conclusion

PIPC appreciates CMS' consideration of our recommendations, offering a holistic approach to improving patient engagement across the agency. Embracing these recommendations will not only strengthen CMS' relationship with stakeholders but also pave the way for more effective and equitable health care delivery, ultimately benefiting patients and the health care system.