



1717 Pennsylvania Avenue, NW, Suite 800, Washington, DC 20006 Phone: 202.827.2100 Web: www.npcnow.org

September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted Electronically via: [regulations.gov](https://www.regulations.gov)

RE: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments (CMS-1807-P)

Dear Administrator Brooks-LaSure:

The National Pharmaceutical Council (NPC) appreciates the opportunity to submit comments regarding the *Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments Proposed Rule*.

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.¹ We have rich experience conducting research and disseminating information about the critical issues of evidence, innovation and the value of medicines for patients.² Our research helps inform important healthcare policy debates and supports the achievement of the best patient outcomes in the most efficient way possible.

We appreciate CMS's commitment to promoting patient-centered and high-quality health care across the country. We aim to provide CMS with feedback and guidance on research relevant to some of the key policies outlined in the PFS proposed rule for calendar year 2025.

¹ About the National Pharmaceutical Council. National Pharmaceutical Council. 2024. <https://www.npcnow.org/about>

² About the National Pharmaceutical Council. National Pharmaceutical Council. 2024. <https://www.npcnow.org/about>

Our comments are as follows:

I. Monitor Impacts of the Inflation Reduction Act

In this proposed rule, CMS is proposing to codify the inflationary rebate provisions in the Medicare Prescription Drug Inflation Rebate Program. As the agency seeks to codify the details of the inflation provisions of the Inflation Reduction Act (IRA), we urge CMS to continue to evaluate the full impact of the IRA on access to medicines. As shown in our prior research, the IRA's Medicare Drug Price Negotiation Program (DNP) may have unintended consequences on the economic incentives surrounding the launch of medicines, including small molecules, in the US.³ Small molecule therapies represent many drugs used to treat cardiovascular, mental health, and oncology conditions.

NPC is also concerned with the growing research suggesting that the IRA's changes to Part D redesign could lead to increased utilization management and narrower formularies among Part D plans. In a recent survey of managed care professionals, representing 310 million US lives, 24% of payers said that they expect significantly narrower formularies as a result of the IRA's Part D changes. In addition, greater than one-third (42%) of payers expect greater utilization management among Part D plans.⁴ Our prior research demonstrates that prior to implementation of the Medicare Part D redesign, access to the first 10 selected drugs for the Medicare DNP was common without step therapy. However, access to certain biologics and oncological drugs without prior authorization was rare.⁵

It is vital that CMS monitor patient access to drugs, including those in the six protected classes of medicines in Medicare, given the potential negative impact from the DNP and Part D redesign. **Based on our research of the potential negative impacts of the IRA on patient access and innovation,⁶ we urge CMS to continue to implement safeguards and oversight mechanisms to protect access and the drug therapy pipeline of innovative medicines.** Increasing oversight of Medicare Part D access through formulary reviews and increased reporting from plans is essential to ensure adequate access to medicines for millions of seniors.

³ O'Brien JM, Motyka J, Patterson J. How The IRA Could Delay Pharmaceutical Launches, Reduce Indications, And Chill Evidence Generation. HealthAffairs Forefront. November 2023. Available at: <https://www.healthaffairs.org/content/forefront/ira-could-delay-pharmaceutical-launches-reduce-indications-and-chill-evidence>

⁴ McCormick B. How Payers Expect the IRA to Financially Impact Medicare Part D Plans. AJMC. Oct. 2023. Available at: <https://www.ajmc.com/view/payers-expect-the-inflation-reduction-act-to-financially-impact-medicare-part-d-plans>

⁵ Patterson JA, Wagner TD, O'Brien JM, Campbell JD. Medicare Part D Coverage of Drugs Selected for the Drug Price Negotiation Program. JAMA Health Forum. 2024;5(2):e235237. doi:10.1001/jamahealthforum.2023.5237

⁶ Patterson JA, Wagner TD, O'Brien JM, Campbell JD. Medicare Part D Coverage of Drugs Selected for the Drug Price Negotiation Program. JAMA Health Forum. 2024;5(2):e235237. doi:10.1001/jamahealthforum.2023.5237; Patterson J, Motyka J, O'Brien JM. How The IRA Could Delay Pharmaceutical Launches, Reduce Indications, And Chill Evidence Generation, Health Affairs Forefront, November 3, 2023. DOI: 10.1377/forefront.20231101.123865; Patterson J, Motyka J, O'Brien JM. Unintended Consequences of the Inflation Reduction Act: Clinical Development Toward Subsequent Indications Am J Manag Care. 2024;30(2):82-86. <https://doi.org/10.37765/ajmc.2024.89495>

II. Guiding Principles for Patient-Reported Outcome Measures in Federal Models, Quality Reporting, and Payment Programs

We appreciate CMS's request for information (RFI) on guiding principles to inform the selection and implementation of patient-reported outcomes-based measures (PROMs) in federal models and other programs. The RFI states that patient engagement may be a guiding principle to the selection of PROMs, where "The measures have been tested to show that the concept is meaningful to patients. Additionally, there is a validated feedback loop on how their patient-reported data is used to drive performance improvement and improvement in individual patient outcomes/experience".⁷ The RFI also states that equity may be a guiding principle, where "Measures selection considers how measurement may ameliorate or exacerbate disparities including but not limited to considerations for language concordance and response rates. Measures may be stratified by subgroup to better understand disparities in response rates and outcomes."

NPC supports the use of patient engagement and equity as guiding principles for selection and implementation of PROMs and PRO-PMs. People with Medicare may prioritize different outcomes, such as symptom relief, improved quality of life, or indirect benefits such as reduced caregiver burden, compared to clinical outcomes like survival or disease progression.⁸ Subgroups of people with Medicare may also have different priorities. Recognizing outcomes that are most important to patients ensures care aligns with patient preferences, values, and goals and can promote stronger patient engagement and better align incentives. Documented heterogeneity in treatment preferences⁹ and effects¹⁰, as well as disparities in health status and access to care, further underscore the need for diverse patient voices. CMS should recognize that a concept that is meaningful to one patient may not be meaningful to all patients and consider a variety of measures for implementation and development to reflect the full breadth of what matters most to patients.

NPC research conducted with Discern Health highlights important recommendations to guide the development and implementation of patient-reported measures.¹¹ While our research focused on oncology, the recommendations can be more broadly applied to CMS's measure development process, supporting the formation of guiding principles. In addition, to NPC resources, we encourage CMS to reference resources developed by organizations, such as the International Consortium for Health

⁷ Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments. Federal Registrar. Vol. 89. Number 147.

⁸ Ciarametaro M, Buelt L, Dubois RW. Getting Value Right: The Case For Indirect Benefits. March 19, 2020. doi:10.1377/forefront.20200310.267867

⁹ Hollin IL, González JM, Buelt L, Ciarametaro M, Dubois RW. Do Patient Preferences Align With Value Frameworks? A Discrete-Choice Experiment of Patients With Breast Cancer. *MDM Policy Pract.* 2020;5:238146832092801; Groothuis-Oudshoorn CGM, Flynn TN, Yoo H II, Magidson J, Oppe M. Key Issues and Potential Solutions for Understanding Healthcare Preference Heterogeneity Free from Patient-Level Scale Confounds. *The Patient - Patient-Centered Outcomes Research.* 2018;11:463–6.; Whitty JA, Fraenkel L, Saigal CS, Groothuis-Oudshoorn CGM, Regier DA, Marshall DA. Assessment of Individual Patient Preferences to Inform Clinical Practice. *The Patient - Patient-Centered Outcomes Research.* 2017;10:519–21.

¹⁰ National Pharmaceutical Council. The Myth of Average Why Individual Patient Differences Matter [Internet]. Washington, DC; 2022 Jan. Available at: https://www.npcnow.org/sites/default/files/2022-01/The_Myth_of_Average_01.2022.pdf

¹¹Schmidt T, Valuck T, Perkins B, Riposo J, Patel P, Westrich K, Basch E, McClellan M. Improving patient-reported measures in oncology: a payer call to action. *J Manag Care Spec Pharm.* 2021 Jan;27(1):118-126. doi: 10.18553/jmcp.2020.20313. Epub 2020 Oct 26. PMID: 33103618; PMCID: PMC10394208.

Outcomes Measurement and the National Health Council, who have developed extensive resources on patient-centered outcomes measures. We encourage CMS to develop guiding principles that:

- Include the diverse perspectives of patients and caregivers throughout measure development, implementation, and evaluation, to ensure measures are meaningful.
- Produce meaningful patient-reported measures and patient-reported performance measures that can be used to meet clinical care, quality improvement, and accountability needs of relevant disease states.
- Produce scientifically sound measures. Appropriate risk adjustment is also needed to avoid negative impacts on providers.
- Minimize patient and provider burden. Standardizing measures across programs is one strategy to reduce this burden.
- Support providers in measure implementation. A lack of provider resources or insufficient incentivizes for provider adoption can pose barriers to the implementation of new measures.

We have seen CMS make efforts to include the patient perspective in other CMS programs; however, more must be done to ensure that the patient voice is prioritized at all stages of healthcare decision-making. Incorporating the patient voice and robustly engaging patients throughout the measure process is another opportunity for CMS to move towards a patient-focused healthcare system.

III. Patient Access and Payment of Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention under Medicare Part B

CMS expects to finalize the National Coverage Determination for PrEP in late September 2024 under which PrEP medicines and related services will be covered under Medicare Part B as a preventative service, without any copayment. In this proposed rule, CMS has outlined a proposed payment methodology for PrEP drugs under Medicare Part B. CMS proposes to set payment amounts for these drugs using the ASP methodology. If ASP data were not available for a given drug, the fee for the administered PrEP drug would be set using the most recent amount published in the National Average Drug Acquisition Cost Survey. **We propose that CMS consider employing a publicly available source of drug pricing information, such as the wholesale acquisition cost (WAC), if ASP is not available to promote transparency and is subject to less variability. WAC is also commonly used as a pricing benchmark in Medicare Part B and should be considered as a preferred pricing benchmark for PrEP preventive therapies in the absence of ASP data.**

NPC supports CMS's efforts to promote access to HIV PrEP drugs with no cost-sharing, which may improve medication adherence. Our prior research has shown that utilization management and out-of-pocket costs worsen adherence to medicines.¹² Although CMS has taken steps to prepare providers and pharmacies for this potential change and has noted the critical importance of uninterrupted access to HIV PrEP drugs and treatments, we urge CMS to take steps to prevent patient access challenges throughout

¹² Fusco N, Sils B, Graff JS, et al. Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: A Systematic Literature Review. *J Manag Care Spec Pharm.* 2023;29(1):4-16. <https://doi.org/10.18553/jmcp.2022.212>

the transition over coverage, if the proposals are finalized.¹³ **Given the clinical and public health considerations related to the prevention of HIV, we suggest that the agency continue to ensure that HIV medicines administered under Medicare Part B have adequate coverage and protections.** Medicare Part D plans are limited in their ability to impose utilization management tools for medicines in the six protected classes. We recommend that similar protections be ensured as preventive HIV medicines transition to coverage under Medicare Part B.

IV. Hepatitis B Vaccine Coverage

The proposed rule includes several proposals that could expand patient access to drugs, including expanded coverage of Hepatitis B vaccines. Under the proposal, the definition of an intermediate risk population for Hepatitis B would also include individuals who have not previously completed a Hepatitis B vaccination series or those whose vaccination status is unknown. The expanded definition of an “intermediary” at risk group for Hepatitis B would expand access to coverage of Medicare Part B beneficiaries. NPC appreciates the agency’s commitment to expanding access to Hepatitis B vaccines and thus improving public health.

Conclusion

The National Pharmaceutical Council appreciates the opportunity to comment on this proposed rule. We would be happy to meet to expand upon our comments and share our research. Please contact me at john.obrien@npcnow.org or (202) 827-2080 if we may provide any additional information.

A handwritten signature in blue ink, appearing to read 'JOHNB'.

John O’Brien, PharmD, MPH
President & Chief Executive Officer

¹³Centers for Medicare & Medicaid Services. Fact Sheet: Potential for Medicare Part B Coverage of Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy (oral or injectable) to Prevent Human Immunodeficiency Virus (HIV). July 2024. Available at: <https://www.cms.gov/files/document/fact-sheet-potential-medicare-part-b-coverage-preexposure-prophylaxis-prep-using-antiretroviral.pdf>