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January 5, 2024

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4205-P
P.O. Box 8013
Baltimore, MD 21244
Submitted electronically via <https://regulations.gov>

RE: Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications [CMS-4205-P]

Dear Administrator Brooks-LaSure:

The National Pharmaceutical Council (NPC) appreciates the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS) notice of proposed rulemaking, *Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications*.

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

Our comments are as follows:

Feedback on Health Equity Analysis of Utilization Management Policies and Procedures

NPC supports CMS's proposal to require Medicare Advantage (MA) plans to conduct an annual health equity analysis of utilization management policies and procedures and encourages CMS to ensure public data from these analyses is transparent and accessible to ensure utility for researchers.

As a health policy research organization, NPC is appreciative of CMS's proposal to require Medicare Advantage Organizations (MAOs) to make the results of health equity analyses public on their website by July 1, 2025. We agree that making this information publicly available may assist researchers such as NPC in developing tools and conducting studies to further inform the public on considerations related to

health equity and utilization management. As part of this proposal, the publicly available information on the MAO website must be “easily accessible and without barriers.” CMS has specified several data considerations related to this provision to ensure accessibility, including making the data free of charge without users needing to create an account or submit personal information and posting the information in a machine-readable format that establishes and maintains automated access. CMS is also considering requiring MAOs to submit the link to the health equity analysis report to CMS, to allow all links to be posted in one place and increase accessibility and transparency.

NPC supports the implementation of these requirements but is concerned that there is no method related to enforcement of these requirements. We urge CMS to develop clear processes and procedures to ensure that organizations are in compliance with these requirements and that there is an opportunity for stakeholders to provide feedback directly to CMS if organizations do not follow these requirements. Such enforcement will be important to ensuring compliance with these requirements particularly given the Government Accountability Office (GAO)’s prior concerns regarding MAOs’ improper denials of prior authorization requests.¹ The data provided by plans in the health equity analysis could be used by CMS to further address and monitor for plans’ use of prior authorization. For example, CMS could audit plans’ compliance with requirements associated with beneficiaries’ access to covered Medicare services and access to drugs if results of the health equity analysis indicate concerns with beneficiary access, or if the plan does not conduct the analysis as required. In addition, CMS should commit to taking timely action to address any systematic problems in plans’ use of utilization management that come to light in these analyses. CMS should extend these provisions beyond MA to apply to Part D enrollees in MA plans as well as MA-PD plans.

To improve the utility of the data for researchers, **we encourage CMS to ensure that the data posted from these analyses is transparent so that researchers understand limitations and underlying assumptions related to the data and are able to conduct additional studies and analyses that allow for comparisons across plans.** For example, information on sample sizes and data exclusions is important for researchers to be aware of to accurately conduct further analyses.

We also ask that CMS require MA plans to provide information on the number of denials, appeals, and approvals after appeals, rather than only percentages, and expand the analysis to include information on drugs with step therapy requirements. We believe the inclusion of this information will better aid CMS and researchers in identifying trends in utilization management.

Finally, we ask that CMS consider requiring demographic information to be collected and included in the health equity analyses. The inclusion of demographic information will better inform researchers’ understanding of how prior authorization may impact health disparities, particularly for historically underrepresented groups. While CMS’s proposed analysis would examine the impact of prior authorization policies on beneficiaries that have at least one of the CMS-defined social risk factors, stratifying this information based on demographic information would further researchers’ understanding of which patients are most impacted by prior authorization and allow for greater comparison across plans.

¹ Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. Government Accountability Office. April, 27, 2022. <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp>

Conclusion

The National Pharmaceutical Council appreciates the agency's commitment to health equity and appreciates the opportunity to provide comments in response to the 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.

Sincerely,

A handwritten signature in blue ink, appearing to read "John M. O'Brien". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

John M. O'Brien, PharmD, MPH
President and Chief Executive Officer