PAN Foundation

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May 29, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare Program; Request for Information on Medicare Advantage Data [CMS-4207-NC]

Dear Administrator Brooks-LaSure,

On behalf of The Patient Access Network (PAN) Foundation, one of the nation's largest charities, I write to provide comment on Centers for Medicare and Medicare Services' (CMS) Request for Information (RFI) regarding Medicare Advantage data. We appreciate your commitment to transparency and enhancing data capabilities in Medicare Advantage.

PAN is an independent, national 501(c)(3) organization dedicated to helping federally and commercially insured people living with life-threatening, chronic, and rare diseases with the out-of-pocket (OOP) costs for their prescribed medications. PAN provides patients with direct assistance through more than 70 disease-specific programs and collaborates with national patient advocacy organizations to provide patients with education and additional support. Since 2004, we have helped more than 1 million underinsured patients.

Improving Prior Authorization Processes

PAN is supportive of any policy changes that streamline prior authorization and remove administrative burdens on providers. That includes instituting data collection and transparency requirements as needed to identify abuses of prior authorization processes and specific areas of concern within such processes.

While prior authorization's goal is to contain health care costs by ensuring that services are medically necessary prior to approval for payment, the requirements currently in place for prior authorization create barriers to care which lead to confusion, delays, and potential harm to patients.[1] As CMS itself has acknowledged, prior authorization has also been identified as a major source of provider burnout and causes providers to expend resources on staff to identify prior authorization requirements that vary across payers and navigate the submission and approval process, which could otherwise be directed to

[1] Jeannie Fuglesten Biniek and Nolan Sroczynski, "Over 35 Million Prior Authorization Requests Were submitted to Medicare Advantage Plans in 2021," Kaiser Family Foundation, February 2, 2023. Accessed at: https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/#:~:text=Prior%20authorization%20is%20intended%20to,covered%20by%20a%20patient's%20insurance.

clinical care.[2] In all, prior authorization can cost an estimated $2,140 to $3,430 annually per full-time physician.[3]

Additionally, and most importantly, prior authorization requirements can lead to poorer health outcomes for patients. For example, a study published in the Journal of Managed Care Pharmacy examined the records of more than 4,000 patients with Type 2 diabetes who were prescribed costly, newer medications requiring prior authorization. Those who were denied the medications had higher overall medical costs during the following year. Failure to receive and take medically necessary medications could be a factor contributing to inadequate control of diabetic conditions, which may result in an excess of resource utilization and increase costs for treating the disease and other comorbidities.[4]

For these reasons, we support the following changes to prior authorization processes:

- **Reducing the administrative burden of providing mental health and substance use care for Medicare patients**. The Mental Health Parity and Addiction Equity Act of 2008 requires that commercial insurers show that their prior authorization policies are no more restrictive for mental or behavioral health services compared to other services. However, no such policy exists for Medicare Advantage. Reducing administrative burdens introduced through prior authorization on mental health services could improve participation among mental health providers.

- **Extending the Interoperability and Prior Authorization Final Rule to include drugs.** While a key step forward, the Prior Authorization Final Rule issued on February 8, 2024 did not include prescription drugs, a prior authorization category that affects a broad swathe of patients. PAN believes there should be limits on step therapy and claim review timing put in place so that patients receive the prescriptions they need as soon as possible.

- **Limiting prior authorization barriers in ERISA plans.** ERISA plans are subject to Department of Labor jurisdiction, but PAN would point out that CMS can and should ease prior authorization requirements when someone switches from an ERISA plan to a non-ERISA plan under CMS regulatory authority like Medicaid or a Marketplace plan. While we thank CMS for acknowledging this issue in the context of Medicare Advantage plans, where it implemented a 90-day grace period, patients should not have to re-do the prior authorization process when switching to a plan under CMS' regulatory jurisdiction.

- **Simplifying the appeals process.** Patients rarely appeal prior authorization claim denials. While it is likely the low number of appeals stems from the time commitment needed, confusion on the part of the patient vis-à-vis what their care provider will do, and/or the paperwork burden, the appeals process remains opaque. CMS should institute transparency requirements to demystify the process.

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[2] CMS. Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule CMS-0057-P: Fact Sheet, December 6, 2022.

[3] Morley CP, Badolato DJ, Hickner J, Epling JW. The impact of prior authorization requirements on primary care physicians' offices: report of two parallel network studies. *J Am Board Fam Med***.** 2013; 26:93–95. doi: 10.3122/jabfm.2013.01.120062

[4] Ani Turner, George Miller, Samantha Clark, Impacts of Prior Authorization on Health Care Costs and Quality, Altarum's Center for Value in Health Care, p. 10, November 2019. Accessed at: https://www.nihcr.org/wp-content/uploads/Altarum-Prior-Authorization-Review-November-2019.pdf.

- **Implementing prior authorization decision-making transparency.** Perhaps the clearest need for additional data collection in prior authorization comes from the lack of transparency in health plans' prior authorization processes. More data will allow patients, providers, and regulators to determine more clearly what, exactly, goes into plans' prior authorization decisions. Plans should be required to disclose their overall rationale, the clinical criteria they use, and the use, if any, of automated or artificial intelligence programs without human review. How clinical coverage criteria are applied is particularly impactful for those seeking mental health services and has been the subject of extensive litigation. Prior authorization decisions should not be a mystery to patients or providers.

Enhancing Data Collection to Advance Health Equity

Health equity is foundational to ensuring high-quality care in the MA program. While existing tools like the Health Equity Index serve to measure disparities, the PAN believes that a more nuanced and comprehensive approach is necessary to capture the full spectrum of factors influencing health equity. To this end, the PAN urges CMS to adopt measures that go beyond current practices by integrating a broader array of social determinants of health (SDOH) data into MA plan assessments. This would include variables such as socioeconomic status, geography, language, and disability status, which are pivotal in understanding and addressing the barriers to equitable care.

Furthermore, we recommend that CMS leverages the newly released Statistical Policy Directive No. 15 to enhance the granularity of race and ethnicity data collection as quickly as possible.[5] By doing so, CMS can identify and address health disparities in more specific and effective ways. Moreover, incorporating these detailed health equity metrics into the overall quality measurement and improvement frameworks used to evaluate MA plans will ensure a holistic view of plan performance, not limited to clinical outcomes but extending to equitable care delivery. Such metrics could include patient satisfaction scores disaggregated by detailed demographic categories, alongside analyses of treatment outcomes by population group.

By enriching the data framework and embedding comprehensive health equity measures into the evaluation process, CMS can ensure that all beneficiaries receive care that is not only clinically effective but also equitable and respectful of their diverse needs. This enhanced approach will not only improve individual health outcomes but also strengthen the systemic health of the entire MA program, fostering a more inclusive health care environment.

Utilize Medicare Advantage Prescription Drug Plans (PDPs) Data to Inform and Improve Outcomes

MA PDPs integrate prescription drug coverage, presenting unique challenges and opportunities for improving health care delivery. PAN notes the critical need for seamless coordination between pharmacy benefits and medical coverage to optimize treatment outcomes and enhance patient care. To achieve this, PAN recommends that CMS mandate clear, accessible information on formulary changes, coverage criteria, and out-of-pocket costs to ensure beneficiaries are well-informed and can manage their health effectively. Further, strong data collection on formulary review processes is crucial to ensure that MA PDPs offer a comprehensive range of essential medications, including access to the latest therapies as they become available. These processes should align with the latest clinical guidelines

[5] Revisions to OMB's statistical policy directive no. 15: standards for maintaining, collecting, and presenting federal data on race and ethnicity, 89 Fed. Reg. 22182 (March 28, 2024).

and be transparent to both providers and beneficiaries, enabling better decision making and adherence to prescribed therapies. Given the significant impact of pharmaceuticals on patient health, particularly for those managing chronic conditions, CMS should also promote best practices among MA PDPs that facilitate enhanced communication and data sharing between health care providers and pharmacists. This integration is vital for preventing adverse drug interactions and ensuring that medication management strategies are as effective as possible.

PAN also recognizes the potential for MA PDPs to contribute significantly to the advancement of value-based care within the MA program. By incentivizing medication use that is aligned with improved health outcomes, CMS can foster an environment that rewards quality and efficiency in pharmaceutical care. Regular reviews and updates to the incentives for MA PDPs that successfully implement these models will be crucial for encouraging ongoing innovation and quality improvements.

Thank you again for the opportunity to comment in response to this RFI. The PAN Foundation appreciates your leadership to increase equitable access to and affordability of health care for more Americans. Thank you for your consideration of our comments. If you have questions about the issues raised, please contact Amy Niles, Chief Mission Officer at aniles@panfoundation.org.

Sincerely,

Kevin L. Hagan
President and Chief Executive Officer