May 28, 2024

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

Submitted via regulations.gov

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

Dear Administrator Brooks-LaSure:

On behalf of the American Association of Psychiatric Pharmacists (AAPP), we appreciate the opportunity to respond to the 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.

About AAPP

AAPP is a professional association of nearly 3,000 members who envision a world where all individuals living with mental illness, including those with substance use disorders (SUDs), receive safe, appropriate, and effective treatment. Pharmacist members specialize in psychiatry, substance use disorders (SUD), and psychopharmacology and most are residency trained and Board certified in psychiatric pharmacy holding the BCPP credential (Board Certified Psychiatric Pharmacist). With a significant shortage of mental health care professionals, psychiatric pharmacists offer another resource to improve outcomes for patients with psychiatric disorders and SUDs.

Role of Psychiatric Pharmacists

Pharmacists graduate with a Doctor of Pharmacy degree, requiring six to eight years of higher education to complete, and have more training specific to medication use than any other health care professional. Psychiatric pharmacists, a specialty within clinical pharmacy have advanced training and expertise to provide direct patient care and medication management for the complete range of psychiatric disorders and SUDs across the lifespan.

Psychiatric pharmacists work in collaboration with the patient and other health care providers including, but not limited to, psychiatrists, other physicians, therapists, social workers, and nurses (including advanced practice nurses). Psychiatric pharmacists provide expert, evidence-based Comprehensive Medication Management (CMM) services for the most complex patients with mental health disorders and SUDs. Psychiatric pharmacists increase capacity of the health care team to provide care and

psychopharmacology expertise, as well as improve patient outcomes and reduce overall health care costs. As medication experts, psychiatric pharmacists are uniquely positioned to facilitate medication access and adherence by identifying and helping to address potential treatment barriers, including prior authorizations and high out-of-pocket patient costs.

Psychiatric pharmacists have a deep understanding of Medications for Opioid Use Disorder (MOUD) that extends beyond that of most other health care providers. When included in the provision of MOUD services through a collaborative practice arrangement, psychiatric pharmacists' involvement has been demonstrated to improve patient adherence and success with buprenorphine treatment for opioid use disorders; reduce per patient dosage of buprenorphine through improved medication management, monitoring and titration; and reduce overall costs. Furthermore, given the insufficient number of providers in addiction medicine, psychiatric pharmacists increase access to SUD treatment by providing medication management, education, monitoring, and follow-up care.

While psychiatric pharmacists are recognized as valued members of interprofessional treatment teams, many also hold decision-making and leadership roles in health care organizations, state and federal organizations, academia, and industry.

Improving Prior Authorization Processes

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

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[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.

[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

Medicare Advantage prescription drug plans cover retail prescription drugs related to mental health and are required to cover all or substantially all antidepressants, antipsychotics, and anticonvulsants, as each is one of the six protected classes of drugs in Part D. Plans are permitted to impose prior authorization and step therapy requirements for beneficiaries initiating therapy (i.e., new starts) for each of these protected drug classes.

Medicare Advantage plans can require referrals and prior authorization for Part A and B services, including mental health and substance use disorder services. In 2022, according to a Kaiser Family Foundation analysis of CMS Medicare Enrollment and Dashboard Files,[4] virtually all enrollees (99%) are in plans that require prior authorization for some services, including for inpatient stays in a psychiatric hospital (94%), partial hospitalization (92%), opioid treatment program services (85%), mental health specialty services (therapy with other mental health providers besides psychiatrists; 85%), psychiatric services (therapy with a psychiatrist; 85%), and outpatient substance abuse services (83%).

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.[5]

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. AAPP believes there should be limits on step therapy and claim review timing so that patients receive the prescriptions they need as soon as possible. Furthermore, mechanisms are needed to reduce provider burden and facilitate access to chronic medications such as not requiring repeat authorizations for a chronic or long-term care condition, including psychiatric disorders and SUDs.

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[4] Meredith Freed, Juliette Cubanski, and Tricia Neuman, FAQs on Mental Health and Substance Use Disorder Coverage in Medicare, January 18, 2023. Accessed at https://www.kff.org/mental-health/issue-brief/faqs-on-mental-health-and-substance-use-disorder-coverage-in-medicare/.

[5] 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.

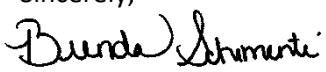
- **Limiting prior authorization barriers in ERISA plans.** ERISA plans are subject to Department of Labor jurisdiction, but AAPP would point out that CMS can and should ease prior authorization requirements when someone switches from an ERISA plan to a non-ERISA plan under CMS regulatory authority like 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.

- **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.

Thank you again for the opportunity to comment in response to this RFI. If you have any questions, please do not hesitate to contact me or our Health Policy Consultant, Laura Hanen at lahanen@venable.com.

Sincerely,



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