



June 15, 2026

Administrator Oz
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via regulations.gov

Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges [CMS-0062-P]

Dear Administrator Oz:

On behalf of the American Association of Psychiatric Pharmacists (AAPP), we appreciate the opportunity to respond to the "Interoperability Standards and Prior Authorization for Drugs" proposed rule. We appreciate your commitment to improving the prior authorization process.

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.

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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.

AAPP Comments to Proposed Rule

AAPP is supportive of any policy changes that streamline prior authorization and remove administrative burdens on providers. While prior authorization's overall 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

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](https://doi.org/10.3122/jabfm.2013.01.120062)

While antidepressants and antipsychotics are protected classes under Medicare Part D, they are subject to prior authorization and step therapy for patients starting treatment for the first time or new starts, thus making it challenging for enrollees to access drugs under the protected classes.⁴

The proposed rule includes several important reforms that may help address these longstanding concerns, particularly through efforts to improve timely access to medications, reduce unnecessary administrative burden, and increase transparency surrounding prior authorization determinations. However, AAPP is concerned that Medicare Part D beneficiaries have been left behind in critical areas of this reform. While the proposed rule extends new protections and transparency requirements to Medicare Advantage, Medicaid, CHIP, and Marketplace plans, similar requirements for Part D sponsors are either absent or weakened, perpetuating longstanding access barriers for Part D enrollees.

1. Timely Access to Psychiatric Medications

AAPP agrees with CMS's efforts to streamline electronic prior authorization processes for prescription drugs and improve the efficiency and timeliness of prior authorization determinations. Patients receiving treatment for mental health and substance use disorders are particularly vulnerable to disruptions in medication access caused by prior authorization requirements. Delays in initiating or continuing treatment with psychiatric therapies can result in symptom relapse, psychiatric hospitalization, overdose risk, and decreased medication adherence. Continuity of these therapies is especially important for patients with serious mental illness, where disruptions in treatment may quickly destabilize otherwise well-managed conditions.

AAPP believes that improving electronic prior authorization processes has the potential to reduce unnecessary delays in care and improve patient outcomes, particularly for individuals requiring ongoing psychiatric treatment.

2. Reducing Administrative Burden Through Standardization and Electronic Prior Authorization

AAPP supports CMS's efforts to modernize prior authorization workflows through standardized electronic processes and interoperability requirements. Psychiatric pharmacists routinely navigate inconsistent payer requirements and repeated documentation requests that consume substantial clinical and administrative resources.

Standardized electronic prior authorization processes have the potential to improve efficiency for providers and payers alike by reducing duplicative paperwork, minimizing manual data entry, and improving communication regarding coverage and documentation requirements. Allowing providers to identify prior authorization requirements and submit requests electronically may help reduce delays, administrative burden, and provider burnout while allowing clinicians to devote more time to direct patient care.

AAPP also remains concerned about the burden associated with repeated prior authorization requests for patients who are receiving long-term psychiatric treatment. Providers are frequently required to resubmit

⁴ [Impact of Protected Class Utilization Management in Medicare Part D](#). Avelere, June 2, 2020.

substantially similar clinical information for medications that have already been approved and demonstrated to be effective for a given patient. CMS should continue exploring opportunities to reduce unnecessary repeat prior authorization requirements where clinically appropriate.

3. Transparency and Communication Regarding Prior Authorization Decisions

AAPP also supports CMS's proposals to improve transparency and communication surrounding prior authorization determinations. Clear and timely communication regarding denials is critical to ensure that providers can respond appropriately, submit additional documentation when necessary, pursue appeals, or consider alternative treatment options without unnecessary delay.

In addition, public reporting of prior authorization metrics may help patients, providers, and policymakers better understand how prior authorization is being used across plans. Increased transparency and accountability are important steps toward identifying inappropriate barriers to medically necessary care and improving the overall prior authorization process for patients receiving behavioral health treatment.

AAPP also encourages CMS to continue advancing transparency regarding the criteria used to make prior authorization determinations, including the use of artificial intelligence. Providers and patients should understand the basis for prior authorization decisions, and any automated processes should be subject to appropriate clinical oversight and human review. This is particularly important in behavioral health, where treatment decisions are highly individualized and often require comprehensive consideration of a patient's treatment history, medication response, and clinical stability.

AAPP Comments on Request for Information on Step Therapy

AAPP appreciates CMS's request for information regarding the use of technology to manage step therapy requirements. While step therapy policies are intended to encourage clinically appropriate and cost-effective prescribing, overly rigid step therapy protocols may create significant barriers to care for patients with mental health and substance use disorders.

Psychiatric treatment is highly individualized, and patients often respond differently to medications within the same therapeutic class. Patients who are stable on a particular medication regimen may experience serious clinical consequences if required to switch therapies or have to prove that alternative medications do not work before accessing the treatment selected by their provider. Treatment disruptions associated with step therapy may cause symptom relapse, hospitalization, medication nonadherence, overdose risk, and other adverse outcomes.

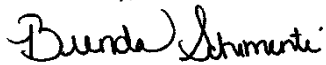
AAPP encourages CMS to consider policies and technological approaches that improve transparency, streamline step therapy exception processes, and reduce duplicative utilization management requirements when patients transition between health plans. For example, electronic health systems that allow providers to quickly identify step therapy requirements and document previous medication trials, failures, prior approvals, and established treatment histories may help reduce administrative burden, minimize delays in care, and improve continuity of psychiatric treatment.

AAPP also encourages CMS to consider the importance of avoiding unnecessary interruptions in treatment within step therapy programs, particularly for patients who are clinically stable on existing therapies. Patients should not be required to repeatedly fail medications or undergo unnecessary treatment disruptions when there is clear clinical evidence supporting continuation of their current therapy.

Conclusion

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

Sincerely,

A handwritten signature in black ink that reads "Brenda Schimenti". The signature is fluid and cursive, with the first name "Brenda" and last name "Schimenti" clearly distinguishable.

Brenda K. Schimenti
Executive Director