June 15, 2026
Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: 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

Dear Dr. Oz,

On behalf of Mindful Choices for ADHD, thank you for the opportunity to respond to the Department of Health and Human Services (HHS) proposed rule titled "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."

Mindful Choices for ADHD (Mindful Choices) is the only nonpartisan, nonprofit organization created to inform national policy about ADHD. We bring together policymakers and advisors with leading clinicians, patients and medical innovators to address pressing challenges for individuals with ADHD and the healthcare system that serves them.

We appreciate CMS's efforts to streamline the prior authorization process, aim to reduce administrative burden, and improve interoperability to ensure that patients maintain timely access to treatment. Below, we offer additional context and recommendations for the proposed rule.

Background

ADHD medication management is highly individualized and requires collaboration between patients, caregivers, and providers over time to identify the most effective

medication, dosage, and formulation for a particular individual. Patients may respond differently to the same medication and finding an effective treatment regimen frequently involves medication changes or adjustments as physicians monitor efficacy and side effects, which may also change over time with ongoing evaluation. Patients often encounter multiple utilization management requirements throughout this process, including step therapy protocols, prior authorization requirements, and other coverage restrictions that can affect access to treatment.

Not only do prior authorization barriers make it more difficult for patients to access clinically appropriate formulations; they also have the effect of steering prescribers and patients towards older, low-cost therapies that may be less appropriate for individual patients – including those which most often lend themselves to misuse or diversion. Newer and more innovative therapies for ADHD are by contrast substantially less subject to misuse, and patient as well as public health goals are best served when we to lower barriers to access when a clinician believes they are appropriate.

For those many ADHD patients whose therapeutic access is affected by prior authorization barriers, these hurdles can delay treatment, interrupt established medication regimens, and undermine long-standing progress in condition management. For all of these reasons, we believe CMS's efforts to reduce unnecessary prior authorization hurdles and improve interoperability have the potential to meaningfully improve continuity of care and access to clinically appropriate treatment for individuals with ADHD as well as to move the needle in reducing inappropriate use of outdated medications. Below we offer several suggestions on the proposed rule.

We urge CMS to strengthen continuity of care protections by removing prior authorization barriers when patients with ADHD transition between providers or health plans.

We appreciate CMS's efforts to enable prior authorization data sharing across Application Programming Interfaces (APIs) and agree that interoperability can support increased visibility into previous approvals and denials to streamline the process. However, we are concerned that the proposed rule does not establish clear continuity-of-care protections for patients who switch providers and/or coverage sources. The proposed rule does not require payers to honor prior authorization determinations made by previous plans or providers, nor does it require payers to recognize prior failed therapies or waive repeat step

therapy requirements based on prior treatment history. With 30-day requirements for each trial, such lack of continuity in the data can cause a disruption for several months.

This is particularly concerning for individuals with ADHD, a condition that often requires patients to spend significant time identifying an effective medication and formulation through trial and error. Disruptions caused by switching providers or changing coverage could result in patients being forced to repeat prior authorization processes or retry medications that were previously ineffective or not well tolerated. Some clinicians have reported situations where patients who changed providers or coverage sources were required to resubmit prior authorization requests or repeat medication trials because prior treatment history was not available to the new provider or plan. Mindful Choices encourages CMS to establish continuity-of-care protections that ensure patients are not required to restart prior authorization or step therapy processes when they transition between providers or payers.

Step therapy can create barriers to timely access to treatment, particularly when patients are required to repeat therapies that were previously ineffective; therefore, we encourage CMS to ensure that step therapy policies for ADHD medications recognize prior treatment history and account for individualized needs. In some cases, patients may be required to try and fail several therapies before gaining access to the medication prescribed by their clinician. These requirements can be particularly challenging in ADHD treatment, where medication response varies substantially from patient to patient. ADHD medication management is often highly individualized and may involve significant trial-and-error to identify the appropriate therapy, dosage, and formulation for a patient. Patients may cycle through multiple medications due to efficacy concerns, side effects, or adherence challenges.

Mindful Choices encourages CMS to clarify that step therapy policies should recognize prior failed therapies, previous step therapy determinations, and established treatment stability, including across payer transitions. CMS should also encourage payers to implement reasonable exceptions processes that account for individualized clinical factors relevant to ADHD treatment (e.g. medication formulation and adherence considerations).

Mindful Choices urges CMS to ensure that patients are not denied access to ADHD treatment because of fragmented or incomplete documentation histories.

We agree that improved access to patient data may help physicians better understand a patient's experience with medications and treatment, but we are concerned about the unintended consequences for patients with incomplete or fragmented medical records. Many Medicaid patients receive care across multiple providers and health systems, meaning that relevant treatment history may not always be captured within a single electronic health record (EHR).

As a result, a patient's full and complete treatment history—including medications they have already tried and failed other medications or previously received authorization for a therapy—may not be captured. In some cases, medication access barriers may occur at the pharmacy level and may not be fully reflected in provider records or administrative reporting systems.

In practice, this may result in patients having to repeat step therapy protocols, submit duplicative prior authorization requests, and/or experience delays and interruptions in access to medications that are already clinically effective. These risks are particularly concerning for individuals with ADHD, where disruptions in treatment can significantly affect school performance, employment, and daily functioning. CMS is in a position to ensure that patients receive timely and clinically appropriate care when records are incomplete or unavailable during provider, payer, or Medicaid eligibility transitions.

We urge CMS to ensure that electronic prior authorization documentation requirements remain clinically appropriate for patients with ADHD.

Mindful Choices appreciates CMS's efforts to streamline prior authorization documentation through interoperable electronic systems, but we are concerned that the proposed rule may unintentionally introduce burdensome documentation requirements. This is particularly relevant for ADHD treatment, which is highly dependent on individualized clinical judgment in terms of medication selection and formulation decisions. For example, some children may require liquid formulations because of difficulty swallowing pills or other adherence-related considerations that may not correspond directly to a diagnostic code. Stakeholders have reported situations where obtaining coverage for clinically appropriate formulations required documentation that did not align with how treatment decisions are actually made in practice. For example,

children who have difficulty swallowing pills and can benefit liquid medications for treatment often have PA requirements of a documented diagnosis of dysphagia, which is a higher bar than many can meet, as they may not have specific muscle or nerve issues.

We are concerned that requiring providers to submit highly specific documentation to justify clinically appropriate treatment choices could create additional barriers to care, particularly for Medicaid patients and pediatric populations already experiencing fragmented care and administrative complexity. We encourage CMS to clarify that documentation requirements used in electronic prior authorization systems should remain clinically appropriate and not require overly specific electronic documentation.

We encourage CMS and CMMI to explore a demonstration project to evaluate whether reducing prior authorization barriers for ADHD medications can support better outcomes.

Given CMS' focus on reducing administrative burdens and improving interoperability, we encourage CMS and CMMI to consider a pilot program within Medicaid and CHIP to evaluate whether reducing prior authorization barriers for clinically appropriate extended-release (ER) ADHD medications improves treatment stability, medication adherence, patient experience, and administrative costs for prescribers.

Insurance practices like prior authorization are particularly impactful in ADHD treatment, where medication management is highly individualized and often requires substantial collaboration between patients and providers. Formulary and utilization management policies may also favor older or lower-cost therapies, including immediate-release (IR) formulations, even when an ER medication may be more clinically appropriate for a patient's individual needs. Therefore, a voluntary pilot program would provide CMS with an opportunity to evaluate whether reducing prior authorization barriers for clinically appropriate ER ADHD medications improves continuity of care, medication adherence, patient outcomes, and provider burden. This pilot could also assess whether improving access to newer more effective treatment options affects prescribing patterns and reduces reliance on therapies that may be more likely to be misused or diverted.

Conclusion

Mindful Choices supports CMS's efforts to modernize and streamline prior authorization processes through improved interoperability and electronic data exchange. Prior

authorization requirements can create significant administrative burden for providers and clinical staff which also can divert resources away from direct patient care and may be particularly challenging for providers managing ADHD patients with complex or highly individualized treatment needs. We appreciate CMS's recognition of these challenges and believe the proposed rule represents an important step toward reducing unnecessary administrative burden and improving the prior authorization process for patients and providers.

We appreciate your consideration of our comments and look forward to opportunities where Mindful Choices can provide appropriate support for those efforts. Please contact Jakara Eason, Executive Director, at jakara@choicesforadhd.org with any questions.

Respectfully,

Jakara Eason

Executive Director