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The Honorable Mehmet Oz, MD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-0062-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

**Re: File Code CMS–0062–P — Interoperability Standards and Prior Authorization for Drugs Proposed Rule**

Submitted electronically via regulations.gov

Dear Administrator Oz:

The American Academy of Sleep Medicine (AASM) appreciates the opportunity to submit comments on the proposed rule addressing interoperability standards and prior authorization processes. The proposed policies will directly impact the care AASM members provide to patients with sleep disorders, as well as the administrative burden associated with delivering that care.

AASM represents more than 9,000 physicians and advanced practice providers, along with 2,400 accredited sleep centers, all dedicated to advancing sleep care and improving sleep health to enhance patient outcomes. Sleep disorders, including obstructive sleep apnea, insomnia, narcolepsy, and hypersomnia, are highly prevalent, frequently comorbid with cardiometabolic and behavioral health conditions, and associated with significant downstream health care costs if left untreated. Policies that streamline access to evidence-based diagnosis and treatment are therefore critical to ensuring timely care, improving clinical outcomes, and reducing long-term health expenditures.

Sleep disorders affect tens of millions of Americans and are associated with substantial morbidity, mortality, and health care costs. Conditions such as obstructive sleep apnea, insomnia, hypersomnia, circadian rhythm sleep-wake disorders, parasomnias, and sleep-related movement disorders contribute to cardiovascular disease, metabolic disorders, workplace injuries, motor vehicle crashes, behavioral health conditions, and diminished quality of life. Timely access to diagnostic testing, durable medical equipment, behavioral interventions, pharmacologic therapies, and longitudinal management is essential to achieving optimal outcomes and preventing avoidable complications.

Sleep medicine clinicians routinely experience a significant administrative burden associated with prior authorization requirements for diagnostic testing, positive airway pressure (PAP) therapy, oral appliance therapy, hypoglossal nerve stimulation, wake-promoting medications, insomnia therapies, and other sleep-related services. As such, AASM strongly supports CMS's efforts to modernize prior authorization processes, improve interoperability, increase transparency, and reduce unnecessary administrative burden across the health care system.

### **Electronic Prior Authorization and Interoperability Standards**

AASM supports CMS's proposals to require implementation of electronic prior authorization processes using standardized application programming interfaces (APIs) and nationally recognized interoperability standards. Adoption of standardized data exchange frameworks has the potential to reduce administrative burden, improve efficiency, and facilitate more timely access to care. However, AASM is concerned that the complexity of the required standards, including multiple FHIR-based implementation guides and National Council for Prescription Drug Programs (NCPDP) transactions, may present operational challenges for specialty practices if not implemented in a coordinated and streamlined manner.

Sleep medicine practices frequently operate in small or resource-constrained settings and rely heavily on electronic health record vendors and payers to implement interoperability requirements. To ensure successful implementation, CMS should provide flexibility in compliance timelines where necessary, particularly for smaller specialty practices with limited technical resources. CMS should also ensure that the technological burden is not shifted onto individual clinicians and should prioritize alignment among required standards to minimize duplicative workflows and support seamless integration with existing clinical systems.

### **Electronic Prior Authorization for Drugs**

The AASM supports CMS's proposal to expand electronic prior authorization requirements to include drugs covered under both medical and pharmacy benefits. Sleep medicine clinicians frequently prescribe medications requiring prior authorization, including treatments for narcolepsy, idiopathic hypersomnia, excessive daytime sleepiness associated with obstructive sleep apnea, insomnia, restless legs syndrome, and circadian rhythm sleep-wake disorders. Current prior authorization processes are often fragmented, payer-specific, and highly manual, resulting in delays in care and a significant administrative burden.

The proposed standardized electronic prior authorization framework has the potential to reduce administrative burden, improve workflow efficiency, and accelerate treatment initiation. To maximize this benefit, AASM encourages CMS to require electronic prior authorization systems to incorporate specialty-specific clinical criteria and to support structured clinical documentation that accurately reflects evidence-based sleep medicine practice. Doing so will help ensure that authorization determinations are aligned with clinical guidelines and reduce unnecessary denials and resubmissions.

AASM also notes CMS's request for comment regarding how drugs are categorized between medical and pharmacy benefits. AASM encourages CMS to ensure that categorization policies reflect real-world clinical practice and clearly identify the appropriate submission pathway for prior authorization requests. Lack of

clarity in benefit categorization can lead to delays, denials, and unnecessary administrative burden for providers and patients alike.

### **Prior Authorization Decision Timeframes**

AASM strongly supports CMS's efforts to establish and harmonize prior authorization decision timeframes across payers. Timely access to therapy is essential in sleep medicine, where delays in treatment can significantly impact patient safety and long-term health outcomes. For example, untreated sleep apnea increases the risk of cardiovascular disease, motor vehicle crashes, workplace injuries, and reduced quality of life, while delays in authorization for wake-promoting medications may impair a patient's ability to safely perform daily activities, including driving or working.

AASM recommends that CMS maintain expedited review pathways for clinically urgent services and therapies and ensure these pathways are applied consistently across payers. CMS should also closely monitor payer compliance with established decision timeframes and enforce requirements that determinations be made as expeditiously as a patient's clinical condition requires. Additionally, CMS should publicly report payer performance regarding turnaround times to promote accountability and transparency. Looking ahead, CMS should consider further reductions in decision timeframes for services with well-established clinical evidence and low rates of inappropriate utilization.

### **Request for Comment: Prior Authorization Timeframes for Drugs**

CMS requests comments on whether there are drugs for which prior authorization decision timeframes currently do not exist. From a sleep medicine perspective, medications used to treat narcolepsy, idiopathic hypersomnia, and excessive daytime sleepiness warrant expedited consideration due to their direct impact on patient safety, occupational functioning, educational performance, and driving ability. Delays in access to these therapies can result in rapid clinical deterioration and increased risk of accidents.

AASM recommends that CMS establish clear and uniform decision timeframes for all drugs requiring prior authorization and ensure that no gaps exist across coverage categories or benefit structures.

### **Transparency in Prior Authorization Denials**

AASM strongly supports CMS's proposal to require payers to provide specific reasons for prior authorization denials. In sleep medicine, denials are frequently associated with unclear or inconsistently applied medical necessity criteria, leading to repeated submissions, prolonged delays in care, and additional administrative burden.

AASM recommends that denial explanations clearly identify the specific clinical criterion that was not met, the evidence or documentation missing from the request, the payer policy used to make the determination, and any alternative pathways that may allow approval. Providing this level of transparency would reduce unnecessary administrative effort, facilitate more efficient resubmissions, promote more consistent application of coverage policies, and minimize delays in patient care.

## **API Endpoint Directory**

AASM supports the proposal requiring payers to report API endpoints and supports the creation of a centralized directory. Sleep medicine practices frequently interact with numerous commercial and government payers, and a centralized directory would meaningfully reduce administrative burden while improving usability and adoption of interoperability tools.

## **Access to Prior Authorization Information Through APIs**

AASM supports CMS's proposal to make prior authorization information available through Patient Access, Provider Access, and Payer-to-Payer APIs. Providing real-time access to authorization status, approval dates, denial reasons, and supporting documentation would improve care coordination, reduce redundant administrative work, and enhance clinical decision-making.

To ensure these tools are clinically meaningful, CMS should require that API functionality support the exchange of documentation commonly used in sleep medicine, including polysomnography reports, home sleep apnea test reports, PAP adherence data, hypoglossal nerve stimulation documentation, actigraphy reports, and validated sleep questionnaires.

## **Public Reporting of Prior Authorization Metrics**

AASM strongly supports public reporting of prior authorization metrics, as greater transparency regarding approval rates, denial rates, appeals, and turnaround times will allow patients, clinicians, employers, and policymakers to better evaluate payer performance.

CMS should consider expanding reporting requirements to include service-specific denial rates, specialty-specific denial rates, rates of overturned decisions following appeal, utilization of peer-to-peer reviews, and rates of automated denials and downcoding. Collectively, these measures would provide a more comprehensive picture of payer behavior and administrative burden.

## **Requests for Information**

### **Electronic Event Notifications (ADT Notifications)**

AASM supports broader use of admission, discharge, and transfer (ADT) notifications and recommends that sleep medicine providers be included among clinicians eligible to receive these notifications. Access to this information would allow sleep specialists to better manage PAP therapy during hospitalizations, coordinate follow-up care after sleep-related motor vehicle accidents, and support patients with complex comorbid conditions such as obesity hypoventilation syndrome, heart failure, and stroke.

## **Cybersecurity and Health Care Resiliency**

AASM strongly supports CMS's efforts to strengthen cybersecurity protections. Sleep centers and physician practices increasingly rely on cloud-based diagnostic platforms, remote PAP monitoring systems,

electronic prior authorization tools, and interoperable data exchange infrastructure. Disruptions to these systems can significantly impair access to sleep testing and treatment.

CMS should promote cybersecurity best practices tailored to small physician practices, encourage standardized security requirements across vendors, support contingency planning for diagnostic and remote monitoring systems, and provide technical assistance resources to ensure that smaller specialty practices can effectively implement and maintain secure systems.

### **Payer API Testing and Certification**

AASM supports stronger oversight of payer APIs, as inconsistent implementation of interoperability standards creates substantial burdens for physician practices attempting to integrate payer workflows into clinical systems. CMS should consider implementing standardized testing requirements, publicly reporting API performance, establishing certification or validation programs, and conducting ongoing compliance monitoring to ensure consistent and reliable functionality.

### **Step Therapy**

AASM supports efforts to improve step therapy processes through interoperability and data sharing. Sleep medicine clinicians frequently encounter step therapy requirements, particularly for wake-promoting medications and other therapies. Patients often change insurance coverage despite stable and effective treatment regimens, resulting in unnecessary treatment interruptions.

CMS should encourage payers to honor prior step therapy completion when supported by interoperable data, minimize duplicate requirements following payer transitions, and utilize Payer-to-Payer APIs to facilitate continuity of care.

### **Laboratory Tests and DMEPOS**

AASM strongly supports CMS's request for information regarding prior authorization requirements for laboratory tests and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). This issue is particularly important in sleep medicine, where PAP devices and supplies, oral appliances, and diagnostic testing services are commonly subject to burdensome authorization requirements.

CMS should reduce unnecessary prior authorization requirements for evidence-based sleep testing and treatment, establish standardized clinical criteria across payers, monitor authorization delays that affect timely PAP therapy initiation, consider exemptions for services with consistently high approval rates, and promote electronic prior authorization workflows that facilitate coordination between DME suppliers and physicians. Addressing these issues is essential, as delays in access to sleep-related DMEPOS frequently postpone treatment initiation, reduce adherence, and negatively impact patient outcomes.

The AASM appreciates CMS's continued efforts to modernize prior authorization and interoperability infrastructure. The proposed rule represents an important step toward reducing administrative burden, improving transparency, enhancing care coordination, and facilitating timely access to medically necessary care. However, careful attention to implementation, workflow integration, and specialty-specific

considerations will be essential to ensure these policies achieve their intended impact. AASM encourages CMS to finalize these proposals while incorporating the recommendations outlined above to ensure that patients with sleep disorders receive timely access to evidence-based diagnostic and therapeutic services.

Thank you for your consideration of these comments. Please feel free to contact Diedra Gray, Director of Quality & Health Policy, at [dgray@aasm.org](mailto:dgray@aasm.org) for additional information or clarification.

Sincerely,

Anita V. Shelgikar, MD, MHPE  
*President, AASM*