March 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS–0057–P. Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

Submitted electronically via https://www.regulations.gov

Dear Administrator Brooks-LaSure:

The American Academy of Sleep Medicine (AASM) appreciates the opportunity to comment on the proposed rule that intends to improve the exchange of healthcare data and streamline processes related to prior authorization, while continuing CMS' drive toward interoperability in the healthcare market. The comments included in this response reflect the needs of our over 10,000 individual members and over 2,500 accredited sleep centers, providing sleep medicine services to the Medicare and Medicaid populations.

Prior Authorization (PA) implementation as a cost-control mechanism prevents timely access to patient care, increases administrative burden on physicians, escalates practice costs, and contributes to physician burnout. The lack of uniformity in PA processes across payers adversely impacts sleep medicine, in particular, as diagnostic testing and medical treatment for sleep disorders requires prior authorization by many payers. According to a Prior Authorization survey[i], by the American Medical Association (AMA), physicians and their staff spend an average of two business days per week completing the PA workload for a single physician, and 88 percent of physicians describe their PA burden as high or extremely high. This translates to less time with patients and contributes to an exhausted and overwhelmed workforce, underscoring the need to reduce overall PA

volume. This survey data also demonstrates that despite the consistent work of state and medical specialty societies, national provider organizations and patient
representatives to convene and collaborate with the AMA to develop best practices for prior authorization, since 2016, there is still more to be done to improve the five clinical categories of best practices for PA, including clinical validity, continuity of care, transparency and fairness, timely access and administrative efficiency, and alternatives and exemptions. AASM continues to support the previously developed AMA framework for PA improvement and urges CMS to finalize proposals to make the PA process more efficient, transparent, and standardized.

Patient Access API

CMS is proposing a January 1, 2026, compliance date for impacted payers to include information about patients' PA decisions in the already-established Patient Access Application Programming Interface (API). The AASM supports the proposal to provide patients with the ability to access prior PA decisions and other health information through the API. However, we recommend that CMS detail how the Agency will ensure patient privacy is protected, through the use of the APIs. We also recommend that CMS identify additional uses for the Patient Access APIs and create educational materials to assist patients in understanding the health care information being provided, including PA information, as well as claims, encounter, and cost data, which will help patients make informed decisions about their care. CMS is also proposing that impacted payers use the Patient Access API to make related administrative and clinical documentation information, including PA requests and decisions for items and services (excluding drugs), available to patients no later than 1 business day after the payer receives the PA request or there is another type of status change for the PA. The AASM agrees that patients should have immediate access to this health information and strongly supports this proposal. Additionally, we encourage the Agency to ensure that patients have access to the same information accessible by providers, as limited and/or partial information may impact patient decisions about their care.

CMS is seeking comment on whether policies should be established to require impacted payers to include information about PAs for prescription drugs. The AASM strongly urges CMS to include information about PAs for prescription drugs in the patient access API and encourages this to be included in future rulemaking. Given the high volume of prescription drugs that require PA, we believe that many patients would appreciate having access to the prescription drug PAs, to understand how payer PA policies may impact provider recommendations and other aspects of the provision of their care.

Provider Access API

CMS is proposing that on or after January 1, 2026, impacted payers would be required to implement and maintain a FHIR API to exchange data with providers and again, AASM strongly supports this proposal. CMS is also proposing that individual patient data maintained by the impacted payer with a date of service on or after January 1, 2016, must be made available via the provider access API no later than 1 business day after the payer receives a request for data from an in-network provider. The AASM supports this proposal, as it will enable the provision of historical healthcare data that may impact current care recommendations and PA practices, as patients have multiple providers and often do not maintain or provide detailed, historical health care data, especially PA data, to new providers. The AASM also supports the CMS consideration to include a requirement for sharing patient data with out-of-network providers, in future rulemaking, as established networks should not determine whether providers have access to data,

which will impact the quality and timeliness of care provided to patients. Providing access to this data, with patient consent, will also greatly improve care coordination, as data will be available to the patients' primary care providers as well as specialists, which may be out-of-network providers, in some instances. CMS proposes that impacted payers would maintain a process to associate patients with their in-network or enrolled providers to enable payers to provide data exchange via the Provider Access API member attribution. The AASM also supports this proposal as this, too, would improve care coordination and prevent delays in data sharing and subsequently, reduce delays in care.

CMS is proposing that impacted payers should be required to maintain a process for patients or their personal representatives to opt out of and subsequently opt into having the patient's health information available and shared via the Provider Access API. CMS is also proposing that these payers make this information available to currently enrolled patients before the Provider Access API is operational and shares any of their data. The AASM fully supports patients' rights to privacy and agree that patients should have the right to opt out of data sharing, via the API. Patients should receive detailed communications regarding the potential benefits and harms of sharing versus not sharing this information, including the potential impact on quality and timeliness of care. This option will contribute to the trend toward greater transparency in healthcare, allowing patients to better understand coverage decisions and how these decisions may impact the care being provided.

Payer-to-Payer Data Exchange on FHIR

CMS is proposing a new policy that would require impacted payers to implement and maintain a Payer-to-Payer API using the FHIR standard and maintain a Payer-to-Payer API that is compliant with the same technical standards, documentation requirements, and denial or discontinuation policies as its Patient Access API requirements. The AASM strongly supports the establishment of a payer-to-payer data exchange, including the use of the FHIR standard, as universal implementation of this standard will define how healthcare information is shared and will have no impact on data collection or storage. We believe that implementation of this HL7 standard will ultimately prevent issues with data sharing across payers and allow information to be shared accurately without delays or technical errors. Additionally, CMS is proposing that impacted payers would implement and maintain a FHIR Payer-to-Payer API to make available all data classes and data elements included in USCDI v1, claims and encounter data, PA requests and decisions, and related administrative and clinical documentation that the payer maintains with a date of service on or after January 1, 2016. Again, the AASM supports the sharing of historical data to increase payer knowledge of previous patient PA decisions and health care data, to encourage continuity of care. CMS is proposing the previous and/or concurrent impacted payer is required to respond to a current payer's request through the Payer-to-Payer API within 1 business day of receipt, which the AASM supports, as this will greatly reduce provider frustration due to delays in response and simultaneous delays in care.

CMS is requesting comments on whether PAs from a previous payer should be honored by the new payer, and if these PAs should be limited to a specific timeframe or focused on specific medical conditions. The AASM believes that changing or revisiting prior PA decisions could delay and/or take away coverage for tests/treatments that were previously approved. Therefore, if payers are not required to honor previous PA decisions, we recommend that impacted payers be required to assess the potential impact to the patient of potentially reversing decisions that could remove effective treatments. The AASM also believes that this potential policy will be challenging due to differences in coverage policies. If, however, payer policies

align, it will be helpful to share the previous payer PA decision so the providers will not have to resubmit the PA information and await a new decision. Payer policies are vastly different, specifically those for diagnostic sleep testing, and we anticipate that PAs being honored by payers may cause confusion for sleep providers, without a mechanism to determine whether the payer PA requirements align. Should a mechanism be created to ensure payer policy alignment, we would support this proposal. We suggest that this data be shared immediately, upon confirmation of the patient identity and upon receiving patient consent.

Improving Prior Authorization Processes

The AASM suggests several improvements to the PA process overall. These include, but are not limited to, the following provisions to improve the coverage criteria used in medical necessity determinations, ensure a clinically sound foundation for PA programs, and protect access to timely care:

- Medicare Advantage plans may only use PA to confirm diagnoses or other medical criteria and ensure the medical necessity of services. ***PA is not to be used to delay or impede medically necessary care.***
- MA beneficiaries must have access to the same care and services they would under Traditional Medicare. When no applicable coverage rule exists under Traditional Medicare, plans must use current evidence from widely used treatment guidelines or clinical literature for internal clinical coverage criteria, which must then be made publicly available.
- MA plans must establish a Utilization Management Committee to review their clinical coverage criteria and ensure consistency with traditional Medicare guidelines.
- MA plans cannot deny care ordered by a contracted physician based on a particular provider type or setting unless medical necessity criteria are not met.

The AASM also urges the finalization of the proposals below to protect patients from care disruptions, treatment delays, and unanticipated medical costs**:**

- MA plans' PA approvals must remain valid for the duration of the course of treatment.
- MA plans must provide beneficiaries with a 90-day transition period where a PA would remain valid for any ongoing course of treatment when beneficiaries change plans or enter MA.
- MA plans cannot retroactively deny coverage for a lack of medical necessity, after PA approval.

CMS included a request for information regarding how to facilitate data exchange between and with behavioral healthcare providers. The sleep medicine community is made of up many specialists, including psychologists, who understand challenges to data exchange first-hand. EHR adoption and implementation has been more limited in behavioral health practices and the AASM encourages the Agency to establish financial incentive programs (i.e., the Health Information Technology for Economic and Clinical Health (HITECH) Act) to support EHR adoption and data exchange in behavioral health settings. In addition to financial incentives, the behavioral health community would also benefit from the development of additional support tools like clinical decision support and business intelligence tools, which would be integrated into the EHR systems and may encourage EHR adoption. Behavioral health providers would benefit greatly from data exchange, having access to PA decision and healthcare data from other behavioral health providers as well as medical providers.

CMS is also seeking comment on how proposals included in this rule can be applied to Medicare FFS. The AASM supports the Agency's efforts to work toward expanding electronic data exchange through implementation of APIs. This will do more to ease the administrative burden on providers and to ensure that high quality care is provided in a timely manner. We believe that providing more resources and incentives to providers and suppliers, coupled with increased education will promote data exchange. The AASM encourages CMS to consider applying the proposed requirements for the Patient Access API and Provider Access API to the Medicare FFS Program, as this would vastly improve data exchange and ultimately, patient care, for Medicare beneficiaries. We also encourage CMS to ensure that Medicare FFS implementation would conform to the same proposed requirements that apply to the impacted payers under this proposed rule.

Thank you for your consideration of these comments. The AASM appreciates CMS' efforts to improve PA processes, by increasing patient, provider, and payer access to electronic health information, prioritizing timely clinical care for patients and allowing providers to focus on the provision of high quality, evidence-based care. Please feel free to contact Diedra Gray, AASM Director of Health Policy, at dgray@aasm.org or 630-737-9700, for additional information or clarifications.

Sincerely,

Jennifer Martin, PhD
AASM President

cc: Steve Van Hout, AASM Executive Director
Sherene Thomas, AASM Assistant Executive Director
Diedra Gray, AASM Director of Health Policy

[i] 2022 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.