September 9, 2024

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–1807–P. Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure:

The American Academy of Sleep Medicine (AASM) appreciates the opportunity to submit comments on the proposed rule for the 2025 Physician Fee Schedule (PFS) and Quality Payment Program. The proposed revisions will directly impact the care provided by AASM members to patients with sleep disorders. The comments included in this response, directly reflect the needs of more than 9,000 individual AASM members and 2,400 AASM-accredited sleep programs, dedicated to advancing sleep care and enhancing sleep health to improve the lives of patients with sleep disorders, including the Medicare population.

A call for CMS to work with legislators to Repair Medicare: 2025 PFS Rate-setting and Conversion Factor and Medicare Physician Payment

The AASM strongly opposes the proposed 2.8% decrease in physician payments for 2025, as the Medicare Economic Index (MEI) predicts that the cost of practicing medicine will increase by roughly 3.6% in 2025. The consistent decrease in physician reimbursement is negatively impacting physician practices and making the practice of medicine unsustainable for many, especially for sleep medicine physicians and qualified health care professionals. A July 2023 survey completed by 197 randomly selected members of the AASM estimated that roughly 33% of responding sleep medicine programs were

concerned about remaining financially solvent through the end of the year. Additionally, a May 2024 survey completed by 165 randomly selected members
of the AASM indicated that 8.5% of AASM members are experiencing occupational burnout due to financial concerns. Financial insecurity has caused more than 150 AASM-accredited sleep facilities to close since 2020, and we anticipate continued facility closures, as physician reimbursements continue to decline, further limiting access to care for patients with sleep disorders.

For the last several years, Congress has enacted the Consolidated Appropriations Act, to relieve some of the strain of the annual Medicare physician payment rate cuts, but this approach is no more sustainable than the annual decrease in Medicare reimbursements for physicians. The AASM now calls on CMS to encourage and work with legislators to establish a permanent fix to this problem, by establishing an annual inflation-based update to the Physician Fee Schedule, which we've advocated for over the past several years, along with the American Medical Association (AMA) and many other medical specialty society organizations. This update would allow physician practices to remain viable and continue to provide high quality care to patients in 2025 and beyond. In the meantime, the AASM also strongly encourages CMS to reconsider finalizing this decreased conversion factor, thereby preventing more facility closures, which ultimately lead to delays in care to the Medicare patient population.

Determination of PE RVUs

Medicare Economic Index and the Physician Practice Information Survey

CMS decided to delay implementation of changes to the Medicare Economic Index upon the encouragement of the AASM and over 170 other healthcare organizations, as the AMA worked to collect updated information via the Physician Practice Information (PPI) survey. The AASM worked collaboratively with the AMA to encourage our members to participate in the survey, which collected data from financial experts at physician practices about cost at the specialty level. This effort was implemented to ensure that the updated MEI weights are based on accurate and up-to-date data, for rate setting. The AASM strongly supports the Agency's decision to delay implementation of the changes to the MEI, as the survey only recently closed, and the data are currently being analyzed.

Evaluation and Management (E/M) Visits

G2211	Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)

CMS is proposing to refine the current policy for services furnished beginning in CY 2025 to allow payment of the Office/Outpatient (O/O) Evaluation and Management (E/M) visit complexity add-on code, G2211, when the O/O E/M base code is reported by the same practitioner on the same day as an Annual Wellness Visit (AWV), vaccine administration, or any Medicare Part B preventive service
furnished in the office or outpatient setting. The AASM supports this proposal, as we agree this will offset previously unaccounted resources inherent in the complexity of longitudinal office visits. However, we believe it is important to emphasize that longitudinal office visits are not limited to primary care but are also relevant to specialty care as well. For example, sleep medicine providers provide longitudinal care for long-term chronic conditions, such as obstructive sleep apnea.

Potentially Misvalued Services Under the PFS

While 95800 has not been flagged as potentially misvalued for 2025, CMS is seeking comments on whether the typical procedure described by CPT code 95800 now involves the use of a disposable home sleep apnea test (HSAT) device rather than reusable equipment. While the AASM is aware that disposable tests are readily available, we do not have access to data to support the nominator's comments, which state that usage is trending more toward the use of disposable equipment. Specifically, the interested party has suggested that CMS delete the WatchPAT 200 Unit with strap, cables, charger, booklet, and patient video (EQ335), Oximetry and Airflow Device (EQ336), and the WatchPAT pneumo-opt slp probes (reusable) (SD263). The interested party suggests that the WatchPAT ONE device (disposable) be added.

When AASM members were last surveyed in 2022, the majority were still using reusable HSAT devices, but we have not resurveyed the membership and cannot confirm the accuracy of the information submitted by the interested party. However, we realize that providers are increasingly incorporating the use of disposable devices into their practices. While a review of home sleep apnea test data from AASM accredited sleep facilities shows an increase in use of disposable HSAT devices from 14% in the first three quarters of 2023 to 22% in the first three quarters of 2024, it does not show that a majority of our members have converted to using disposable HSAT devices. We encourage a data collection process to confirm whether the typical practice is now using disposable devices. Additionally, we do not support the interested party's recommendation to remove the Oximetry and Airflow device (EQ336), as this device would still be necessary to use with other devices reported using 95800, to measure airflow.

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (Section II.D.)

Telemedicine Evaluation and Management (E/M) Services

The AASM strongly encourages CMS to recognize and reimburse the new CPT codes for the synchronous audio-video and audio-only Evaluation and Management (E/M) services as of January 1, 2025. These codes accurately describe telemedicine office visits while also taking the confusion and administrative burden out of reporting these visits, given the time ranges and accuracy in describing resource costs. The AASM supports the RUC recommendations, as submitted, and emphasizes that the recommendations were developed with input from the CPT Editorial Panel, as well as the RUC, which reviewed data from practicing physicians and other health care professionals from many different specialties. The AASM also does not believe these codes are duplicative of the office/outpatient E/M services, as these services are provided remotely, do not require as many cost inputs, and can originate from any site. Lastly, assuming that the telehealth flexibilities that were established as a result of the public health emergency (PHE) are going to expire at the end of the year, telehealth services are going to be limited to patients in rural areas and very specific medical settings. These codes would make care accessible from any location.

Expanded Coverage for Audio-Only Communication Technology

As of 2022, CMS began allowing the permanent use of audio-only equipment for telehealth furnished to established patients at home, for diagnosis evaluation, and treatment of mental health disorders. CMS is now proposing to extend the policy allowing use of audio-only technology when any telehealth service is furnished to a patient in their home, as long as modifier 93 is appended to the claim. The AASM membership is made of up physicians that are board-certified in multiple specialties, and while

our members board-certified in psychology and psychiatry have been benefitting greatly from this policy modification since 2022, more members would benefit from the use of audio-only communications for patients with sleep disorders. The AASM strongly supports the CMS proposal to extend the policy allowing use of audio-only technology and strongly urges CMS to finalize this proposal.

Direct Supervision via Communications Technology

Under Medicare Part B, some services, including diagnostic tests, services incident to physicians' or practitioners' professional services, and other services, are required to be furnished under specific minimum levels of supervision by a physician or practitioner. Outside the circumstances of the PHE, direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service. CMS has previously noted that there is concern about an abrupt transition to pre-PHE direct supervision requirements, since many providers and practices have modified their workflows to allow for supervision via audio and video communications technology, in lieu of in-person supervision. In continuing to focus on increasing access to care, the AASM strongly supports the CMS proposal to permanently allow physicians to be immediately available for direct supervision via audio-video real-time communications technology for a subset of services, and also supports the proposal to continue allowing virtual direct supervision for all other services through 2025. However, we encourage CMS to continue considering allowing direct supervision to be permanent for all non-emergency services.

Supervision of Residents by Teaching Physicians via Communications Technology

CMS is proposing to continue allowing virtual supervision of residents through 2025, which will allow physicians to supervise services provided by residents using audio-video communication technology when the service is furnished virtually. While this is helpful, the AASM is again focused on increasing access to care, given the limited number of sleep medicine specialists available to care for patients. The AASM maintains that providing virtual supervision is helpful in extending training opportunities and may ultimately increase access to care, especially in sleep medicine and other specialties. Unless CMS has received data indicating that virtual supervision has led to patients no longer receiving the same safe, high-quality care as patients receiving care when in-person supervision is employed, we see no reason to revert to the in-person requirement. We, therefore, strongly encourage CMS to instead make this policy permanent and to also expand this flexibility to residents providing in-person services as well, for non-emergency patients.

Reporting of Physician Home Addresses

In 2023, CMS shared a proposal that would require physicians who provide telehealth services from home to report their home addresses to CMS. The AASM urged CMS not to implement this policy, citing concerns about privacy and safety, especially for physicians who provide behavioral health services, as many AASM members do currently. While the AASM supports the CMS decision to not require physicians to report home addresses through the end of 2025, we still strongly urge CMS to allow physicians to provide telehealth visits without having to publicly display their home address on Medicare websites that include a physician lookup feature, due to privacy and safety concerns. We encourage CMS to finalize not requiring this information be made publicly available, rather than extending the delay to the end of 2025.

Advancing Access to Behavioral Health Services

Digital Mental Health Treatment (DMHT) Devices
The Agency is proposing to create three G codes for digital mental health treatment:

HCPCS Code	Descriptor
GMBT1	Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan for furnishing a DMHT device
GMBT2	First 20 minutes of monthly treatment management services directly related to use of the DMHT device
GMBT3	Each additional 20 minutes of monthly treatment management services directly related to DMHT device

We appreciate the agency's proposal to establish codes for payment of digital mental health treatment devices, which includes onboarding, education, supply of the device, and professional services, as this technology can be used for treatment and management of multiple disorders. We do, however, recommend a modification in the categorization of these codes to **Digital Behavioral Health Treatment**, as this broader terminology would allow these codes to be reported for more conditions, including insomnia. We also recommend modifying the code descriptors to include devices that do not automatically transmit data to providers, as there are many devices that don't have the auto transmit feature and require more patient communication. Lastly, we strongly support collecting invoices for national rate setting for GMBT1. If invoice collection is not feasible, we suggest using a crosswalk to set a national rate.

The AASM also believes that CMS should provide explicit reporting instructions to clarify the appropriateness of reporting these three proposed G codes versus the existing remote therapeutic monitoring codes, which were established for reporting when the device has a therapeutic intervention functionality. Sleep medicine providers are well-versed in trying to distinguish between the appropriateness of reporting CPT and G codes, for diagnostic testing for obstructive sleep apnea, as 95800, 95801, and 95806 were established to take the place of G codes G0398, G0399, and G0400. However, these G codes were never retired, despite the establishment of CPT codes, creating confusion amongst the specialty regarding which codes should be reported for these diagnostic tests. If finalized, we recommend an FAQ document, similar to the one established for G2211, to assist certified coders and providers in identifying which codes to report in different clinical scenarios.

Request for Information: Services Associated with Furnishing Oral Appliances Used for the Treatment of Obstructive Sleep Apnea

CMS is requesting information regarding the types of services furnished by a dentist or other practitioner related to oral sleep apnea appliances. The Agency is also requesting details and information regarding the services related to the furnishment of oral appliances used to treat obstructive sleep apnea.

Patient eligibility criteria: to whom is the service related to the furnishing of oral appliances being provided? How is the nuisance snorer differentiated from the medical condition of sleep apnea? What

criteria are used to determine whether the provision of these services may be medically reasonable and necessary?

The AASM Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy recommends that sleep physicians prescribe oral appliances for adult patients who request treatment of primary snoring (without obstructive sleep apnea)[i]. The guideline also recommends that sleep physicians consider prescription of oral appliances for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy. Oral appliances (OAs) reduce the frequency and intensity of snoring, improve sleep quality for both patients who snore and their bed partners, and improve quality of life (QOL) measures. Though the available evidence on these outcomes is limited, this is a standard strength recommendation, as the possible benefits from treatment of primary snoring clearly outweigh the risk. Insufficient evidence exists to conclude that treatment of primary snoring improves other health-related outcomes, or to compare objective sleep quality during use of oral appliances versus other treatments. Therefore, OAs should be recommended to patients who snore, who fail conservative measures (such as weight loss, positional therapy, and avoiding alcohol), and request further treatment. Diagnosis of primary snoring should be rendered by a sleep physician and not a dentist, as snoring is frequently accompanied by OSA, and misdiagnosis can have serious implications for the patient.

Practitioner type: Who provides these services? What credentialing is required? Is supervision required? Who would be billing for these services? Would incident to payment policy rules apply?

The AASM Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy recommends that qualified dentists provide oversight of oral appliance therapy in adult patients with obstructive sleep apnea to survey for dental-related side effects or occlusal changes and reduce their incidence. Although not all-inclusive, desirable qualifications of a 'qualified dentist' include that they have at least one of the following: certification in dental sleep medicine by a non-profit organization, designation as the dental director of a dental sleep medicine facility accredited by a non-profit organization, or a minimum of 25 hours of recognized continuing education in dental sleep medicine (e.g., American Dental Association Continuing Education Recognition Program [ADA CERP] or Academy of General Dentistry Program Approval for Continuing Education [AGD PACE]) provided by a dental sleep medicine focused non-profit organization or accredited dental school in the last two years. A qualified dentist will have the skills to choose the proper OA and make necessary modifications to accommodate patients who, among other things, may have allergies to metals or acrylics, are strong teeth grinders, or have anatomical deviations.

Location of services: Where and how are services for oral sleep apnea appliances provided? Are all services provided in an in-person setting? Does the patient have to be present for all elements of this service? Does the service involve direct contact with the patient in each instance?

The AASM Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy recommends that when oral appliance therapy is prescribed by a sleep physician for an adult patient with obstructive sleep apnea a custom, titratable appliance should be used over a non-custom oral device. Customization may require an in-person visit.

The aforementioned guideline also suggests that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy for patients with oral appliances. Additionally, the AASM Clinical Guidance Statement on Use of Polysomnography and Home Sleep Apnea Tests for the

Longitudinal Management of Obstructive Sleep Apnea in Adults recommends follow up PSG or HSAT to assess response to treatment with non-PAP interventions[ii]. Whether this testing would be conducted in a sleep facility would be determined by the patient's medical history and whether they have mild, moderate, or severe OSA. The AASM Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea recommends polysomnography or home sleep apnea testing with a technically adequate device be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA[iii]. However, polysomnography is recommended in patients with significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or suspicion of sleep related hypoventilation, chronic opioid medication use, and/or history of stroke or severe insomnia.

Lastly, the AASM guideline suggests that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for OSA to return for periodic office visits with a qualified dentist and sleep physician. Again, whether these visits are conducted via telehealth or in-person would largely depend on the patient's medical history and any complications of therapy.

Updates to the Quality Payment Program

MIPS Value Pathways Development and Maintenance

CMS is proposing six new MIPS Value Pathways (MVPs) that focus on multiple specialties, including Complete Opthalmologic Care, Dermatological Care, Gastroenterology Care, Optimal Care for Patients with Urologic Conditions, Pulmonology Care and Surgical Care. The AASM strongly supports the implementation of condition-specific MVPs as they provide reporting opportunities for specialties that sometimes struggle to identify quality measures and improvement activities that are relevant to their specialty. The Pulmonology Care MVP directly impacts sleep medicine, as many sleep medicine physicians are also board-certified in pulmonology and several sleep medicine-specific quality measures are included. We appreciate the Agency's efforts to expand the program to include quality measures and improvement activities that focus on more than conditions managed by primary care providers and agree that this expansion supports the CMS National Quality Strategy, which aims to promote the highest quality outcomes and safest care for all individuals.

The Role of MVPs in Transforming MIPS

The Agency describes their initiative to incrementally develop and maintain MVPs that are relevant and meaningful to support a full transition to MVPs. While the AASM appreciates the existing flexibility, allowing eligible clinicians time to familiarize themselves with MVP policies and to prepare to report MVPs, we strongly disagree with making MVP reporting mandatory and urge CMS to maintain the traditional MIPS program. Over the years, CMS has transitioned from the Physician Quality Reporting Initiative to the Physician Quality Reporting System to the system that is in place now based on implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Each time there is a major change to reporting requirements, there are increases to both administrative burden and cost for eligible clinicians. Physician burnout is consistently increasing as there are efforts to secure a positive adjustment based on participation in the ever-changing Quality Payment Program, which has led to many deciding to simply accept negative payment adjustments or only accept private insurance or self-pay, rather than participate. The AASM strongly encourages CMS to continue traditional MIPS, while incentivizing participation in MVPs. We do, however, support continued development of MVPs for specific health conditions that largely impact the Medicare

population, and encourage CMS to engage multiple specialties in developing condition-specific MVPs so they are reflective of the coordinated care patients receive.

Pulmonology Care MVP

The AASM is excited to have had an opportunity to provide feedback on the Pulmonology Care MVP, as it was being drafted. Sleep medicine providers routinely struggle with identifying measures that are relevant to the specialty and the two measures included in this proposed MVP, measure Q277 (Sleep Apnea: Severity Assessment at Initial Diagnosis) and Q279 (Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea Therapy) are the only two sleep-specific measures in the program. Again, many sleep medicine providers are also board-certified in pulmonology, therefore, we strongly support the inclusion of the Pulmonology Care MVP in the Quality Payment Program.

MIPS Performance Threshold

CMS is proposing to maintain the MIPS performance threshold at 75 points during the 2025 performance period. While the AASM remains supportive of maintaining the MIPS program, we encourage CMS to consider projected impacts to small practices and the potential impact on specialists that are seeing record shortages on support staff and increased costs to providing high quality care to Medicare patients. We encourage CMS to consider putting a multi-year freeze on the performance threshold until Congress can address the rising cost of care and impact on physician reimbursement.

Data Completeness Criteria in the Quality Performance Category

The Agency is proposing to maintain the data completeness criteria at 75% in the quality performance category. This criterion was increased to 75% as of the 2024 performance year, further exacerbating the administrative burden and increased costs associated with participating in the MIPS program. Given the financial challenges many practices are experiencing at this time, we encourage CMS to walk back this criterion to that of the previous year, 70%. In the meantime, we request CMS to consider how to make participation less burdensome and encourage increased collaboration in the areas of interoperability and data privacy, given recent cybersecurity issues and concerns.

Request for Information: Building Upon the MIPS Value Pathways Framework to Improve Ambulatory Specialty Care

The AASM appreciates the Agency's dedication to supporting value-based care and working to align with the National Quality Strategy. However, we strongly oppose any future pay for performance programs with mandatory participation for specialists. Although the intention of incentivized participation in national quality reporting programs is to facilitate an improvement in quality outcomes, providers are struggling administratively and financially to continue participation in MIPS as is. We, instead suggest CMS continue increasing engagement with specialty providers to get feedback on how to move forward without adding more administrative burden and cost and focus on providing adequate reimbursement for current services.

Thank you for your consideration of these comments. The AASM appreciates the Agency's efforts to revise the Medicare Physician Fee Schedule in a way that prioritizes high quality clinical care for patients and fair reimbursement for providers, while working to reduce administrative burden. We encourage the Agency to adopt the recommended changes summarized in this letter. Please feel free to contact Diedra Gray, AASM Director of Quality & Health Policy, at dgray@aasm.org or 630-737-

9700, for additional information or clarifications.

Sincerely,

Eric Olson, MD
AASM President

[i] Ramar K, Dort LC, Katz SG, Lettieri CJ, Harrod CG, Thomas SM, Chervin RD. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. *J Clin Sleep Med* 2015;11(7):773–827.
[ii] Caples SM, Anderson WM, Calero K, Howell M, Hashmi SD. Use of polysomnography and home sleep apnea tests for the longitudinal management of obstructive sleep apnea in adults: an American Academy of Sleep Medicine clinical guidance statement. *J Clin Sleep Med*. 2021;17(6):1287–1293.
[iii] Kapur VK, Auckley DH, Chowdhuri S, Kuhlmann DC, Mehra R, Ramar K, Harrod CG. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med.* 2017;13(3):479–504.