

September 13, 2021

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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–1751–P. Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

The American Academy of Sleep Medicine (AASM) appreciates the opportunity to comment on the proposed rule for the 2022 Physician Fee Schedule (PFS) and Quality Payment Program. The proposed revisions will directly impact the care provided by AASM members, as well as their reimbursements, during the public health emergency and beyond. The AASM is dedicated to advancing sleep care and enhancing sleep health to improve lives, and the comments included in this response reflect the needs of more than 9,000 individual AASM members and 2,500 AASM-accredited sleep centers, providing sleep medicine services to the Medicare population.

II. Provisions of the Proposed Rule for the PFS

Application of Budget Neutrality to Adjustment of RVUs

The AASM strongly opposes the proposed 3.75% decrease in the Medicare conversion factor, due to budget neutrality. While we understand that budget neutrality is required due to the changes in reimbursement for office/outpatient visit Evaluation and Management (E/M) codes, the AASM urges the Agency to advocate for a delay in the additional decrease, due to the far-reaching and lingering financial impact of the COVID-19 pandemic/public health emergency (PHE). AASM members continue to provide feedback that practices have not yet recovered from the

financial losses associated with the PHE and additional decreases at this time may make smaller physician practices less sustainable. Sleep medicine physicians continue to be concerned that patient volumes have only partially recovered since the rollout of COVID-19 vaccines, there are limited reimbursements for personal protective equipment, and that mitigation strategies in many areas across the country are ineffective, given the recent surge in COVID cases, due to the Delta variant. It remains clear that the ongoing PHE will have long-lasting effects on the United States health care system and additional reductions in reimbursements at this time could be devastating. In addition to the reduction in the conversion factor, physicians are also facing other looming payment cuts that require Congressional action to be averted. These payment reductions include expiration of the moratorium on the 2 percent Medicare sequestration at the end of CY 2021 and statutory sequestration cuts of 4 percent required by Pay-As-You-Go legislation, which were triggered by the significant additional spending in the American Rescue Plan, enacted in March 2021. Collectively, physicians are facing payment reductions that total 9.75 percent. These payment reductions come at a time when physician practices are facing uncertainty about the future of the pandemic recovery, telehealth services and growing regulatory burdens. **Therefore, we strongly urge Centers for Medicare & Medicaid Services (CMS) to use its authority to delay these decreases in reimbursement and to maintain current physician payment rates.**

Determination of PE RVUs (Section II.B.)

Market-Based Supply and Equipment Pricing Update

AASM understands the Agency's goal to gather data to support updating the PFS direct Practice Expense (PE) inputs for supply and equipment pricing, especially given that the supply and equipment prices were last systematically developed in 2004-2005. We certainly appreciate the 4-year phase in of the new pricing. However, the decrease in the equipment pricing for home sleep apnea testing code 95806, *Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort (e.g., thoracoabdominal movement)* has already started to have a negative impact on sleep practices. **While we realize supply and equipment pricing cannot remain static, the AASM encourages CMS to develop an ongoing process to update pricing for supplies and equipment, as this will ensure that the supplies and equipment are priced appropriately, going forward.**

Telehealth and Other Services Involving Communications Technology, and Interim Final Rule with Comment Period for Coding and Payment of Virtual Check-in Services--Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (Section II.D.)

Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis

The AASM appreciates the Agency's effort to extend the amount of time allotted for stakeholders to compile, analyze and submit data to support the permanent addition of services to the Telehealth

services list, via the regular consideration process, including notice and comment rulemaking. **However, we strongly suggest the Agency also consider the data collected throughout the PHE to further support the permanent addition of these services to the Telehealth list.** In addition to the codes meeting the CMS criteria to be temporarily added to the Telehealth list initially, sleep disorder patients have had increased access to care through telehealth visits, as telehealth implementation has:

- Improved road safety, by allowing patients that experience drowsy driving (e.g., patients with narcolepsy, obstructive sleep apnea) to see their sleep medicine providers virtually
- Eliminated travel for patients that live a long distance from their sleep medicine provider, particularly those that do not reside in a rural setting
- Reduced reliance on caretakers, family members, and friends to drive elderly and/or patients that are mobility impaired to an office visit
- Reduced risk of exposure to illnesses, in this case COVID-19, for patients that are immunosuppressed or immunocompromised

Additionally, the AASM recently reached out to CMS, regarding the roughly 2 million Philips Respironics devices in use in the United States, for the treatment of obstructive sleep apnea (OSA) being recalled, including continuous positive airway pressure (CPAP), bi-level positive airway pressure (BPAP) devices, and mechanical ventilators devices. These devices are being recalled due to two issues related to the polyester-based polyurethane (PE-PUR) sound abatement foam used in Philips continuous and non-continuous ventilators, and at this time, it is unclear how long it will take for Philips to process claims of recalled machines and provide replacement devices or parts. **Given this ongoing problem for OSA patients, AASM feels strongly that making the additions to the Telehealth list permanent will allow patients to have existing equipment repaired or receive new equipment from DME suppliers much faster and much more efficiently.** CMS may also consider how permanently increasing telehealth services will continue to benefit patients, in the future.

We also urge CMS to continue to include the services 99441 – 99443, the Office/Outpatient telephone evaluation and management services, to the Medicare telehealth list on a Category 3 basis to allow for additional data collection for CMS consideration, as a part of the rulemaking process. We believe that there will be adequate data to support the continuation of these services as telehealth services, given the increased use amongst patient populations with limited access to both in-person care and/or audio/visual technology (e.g., computers, smart phones, broadband/internet access).

Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA)

Per the Agency's request for comments, the AASM supports the development of a claims-based mechanism to distinguish between the mental health telehealth services that are within the scope of the CAA amendments and those that are not. This mechanism would provide clarity for mental health professionals and ensure that services are being billed appropriately. **The AASM suggests**

that a modifier be implemented to identify the services that are within the scope of the CAA amendments.

With regard to the CMS proposal that an in-person visit be required for a beneficiary within a 6-month period prior to the date of the telehealth service, the AASM is concerned that the in-person visit may not be feasible. In instances where patients are unable to attend an in-person visit within that timeframe, they would essentially be penalized and not allowed to receive care via a telehealth visit. **This scenario, again, speaks to the issue of access to care, and the AASM strongly urges CMS to reconsider this proposal or, at a minimum, allow exceptions for those with access issues.** Mental health services, for example, are in even greater demand now, given the impact of the PHE, and patients should not be required to attend an in-person visit in order to receive care.

CMS is also seeking comment regarding whether the required in-person, non-telehealth service may be furnished by another physician or practitioner of the same specialty and same subspecialty within the same group as the physician or practitioner who furnishes the telehealth service. If CMS finalizes that the in-person visit is required, we believe it should be able to be furnished by another physician or practitioner, as outlined, to further limit issues with access to care. **We believe that CMS should harmonize the requirements for these telehealth visits with the requirements for distinguishing E/M services for an established patient, for consistency, which is *one who has received professional services from the physician/qualified health care professional or another physician/qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past three years.*** We also urge CMS to apply this rationale to the instance in which a patient routinely receiving mental health services from one practitioner in a group might have occasion to see a different practitioner of the same specialty in that group for treatment of the same condition.

Additionally, the AASM supports the CMS proposal to identify the home of a beneficiary as an originating site for telehealth services for the diagnosis, evaluation, or treatment of a mental health disorder, effective for services furnished on or after the first day after the end of the PHE. **We also encourage CMS to carry this proposal forward for all services temporarily added to the telehealth services list during the PHE, to further address issues with access to care.**

Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology

CMS's proposal to revise the definition of interactive telecommunications system to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients when the originating site is the patient's home will also improve patients' issues with access to care, and the AASM strongly supports this proposal.

With regard to the CMS proposal to limit payment for audio-only services to services furnished by physicians or practitioners who have the capacity to furnish two-way, audio/visual telehealth services but are providing the mental health services via audio-only communications technology due to patient limitations to access or preferences, the AASM believes this requirement will limit the provider's input regarding whether audio/visual telehealth services are required for specific patients interactions. Providers have historically made decisions regarding whether they need to see a patient in-person and should be able to use their professional judgment in these instances as well. **We suggest that documentation of the patient preference is required only in the instance that the provider recommends audio/visual services and the patient declines. We also urge CMS to reconsider the position of allowing patients to make the initial decision regarding audio-only telecommunications, as not only could this impact patient care but may also lead to unnecessary administrative burden/documentation requirements if detailed documentation is required for each patient that receives audio-only services.**

CMS is also seeking comment on whether higher level services should be excluded from audio-only services. **The AASM, again, recommends that CMS allow clinicians to use their professional judgment in determining whether an audio-only telecommunications service is appropriate.** Mental health professionals are capable of identifying when they need to see a patient, as is true with other clinicians. A visit that requires more time may not necessarily require audio/visual telecommunications. Additionally, patients that require mental health services are not always able or willing to go in for an office visit. Therefore, limiting their access to care may potentially be dangerous. Lastly, providers may spend more time speaking with a patient than anticipated and placing a limitation on higher level visits may encourage some clinicians to limit patient communications if they would not be able to bill for the appropriate, high-level visit when providing audio-only services.

Other Non-Face-to-Face Services Involving Communications Technology under the PFS

Expiration of PHE Flexibilities for Direct Supervision Requirements

The AASM continues to support the PHE flexibilities for direct supervision requirements and strongly urges CMS to make the flexibilities permanent, given the successes demonstrated during the PHE. The flexibilities have increased communication amongst clinicians and their residents, allowing them to provide guidance in many different scenarios, using audio/visual telecommunications. However, we do not agree that the flexibility should only be applicable to a subset of services. **Rather we propose that there be a subset of services for which direct supervision through audio/visual telecommunications services is not appropriate.** In high-risk patients and specific scenarios (e.g., surgical procedures), we support in-person supervision. We also support the creation of a modifier to easily identify these services for which direct supervision through audio/visual telecommunications services is not appropriate, as well as requiring appropriate documentation, including the name of the resident and supervising physician.

Interim Final Provisions in the CY 2021 PFS Final Rule

The AASM strongly supports the CMS proposal to permanently adopt payment for G2252, (Brief communication technology-based service, e.g., virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion). We agree that payment for a longer virtual check-in has been helpful in determining whether an in-person visit is necessary, in some instances.

Valuation of Specific Codes (Section II.E.)

Drug Induced Sleep Endoscopy (CPT code 42XXX)

The AASM has followed the life cycle of code 42XXX since its initial introduction to the CPT Editorial Panel and throughout the RUC review process. **We strongly agree with the CMS proposal to implement the RUC-recommended work RVU of 1.90 for 42XXX and support the RUC-recommended direct PE inputs as well.**

Hypoglossal Nerve Stimulator Services (CPT codes 645X1, 645X2, and 645X3)

The AASM strongly disagrees with CMS calculating intra-service time ratios to account for changes in time for code 645X1. After observing the RUC review of the robust survey data, we agree with our Otolaryngology colleagues that the survey median is more appropriate, given the physician work, intensity, and complexity of the service. We do not agree with the CMS methodology of proposing a work RVU, based on an intra-service time ratio. **The AASM fully supports the RUC-recommended value of 16.00 work RVUs for CPT code 645X1 and urges CMS to accept this value.**

The AASM also strongly disagrees with the CMS proposal of 14.50 work RVUs for code 645X2. CMS proposed this value based on another methodology not used or supported by the RUC, applying incremental differences to value services within the same code family, to maintain an appropriate intra-family relativity. **The AASM completely disagrees with this methodology and urges CMS to finalize the RUC-recommended work RVU of 16.50, the survey median.** This RUC-recommended value is based on survey data from Otolaryngologists who are currently providing the service. The RUC continues to follow a consistent methodology for valuing codes by evaluating work and time, which the AASM supports. We also urge CMS to consider employing more consistent methodologies for valuing newly established codes.

We, once again, strongly disagree with the CMS methodology of using incremental differences within code families to determine the work RVU for 645X3. As previously stated, the RUC employs a very elaborate survey methodology to consider both work and time in making recommendations for code values, and 645X3 was no exception, given the intensity and

complexity of the code. **We, therefore, urge CMS to finalize the RUC-recommended value of 14.00 for 645X3.**

Comment Solicitation for Impact of Infectious Disease on Codes and Ratesetting

The Agency is requesting comments regarding additional strategies to account for PHE-related costs. **The AASM continues to urge CMS to immediately implement and provide separate payment for CPT code 99072 Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious diseases, with no patient cost-sharing. We also recommend that the code not be subject to budget neutrality.** The CMS decision to finalize this code as a bundled service, on an interim basis, was very disappointing. Again, as was obvious from the previously submitted RUC survey data, many physician practices are struggling to continue providing services throughout the ongoing PHE, due to additional direct and indirect costs for PPE, changes necessary to offices and facilities to implement safety measures such as social distancing, and additional cleaning supplies, etc., required for infection control. These extra costs to practices are an additional burden, compounded by the already reduced revenue, as patient volumes are still recovering. The additional expenses are not currently included or captured in any other existing CPT codes, including the E/M services codes. Therefore, we request the Agency's support in providing fair compensation for the essential precautions implemented to provide safe environments for both clinicians and patients, so providers can deliver safe, effective medical care throughout this ongoing pandemic.

Payment for the Services of Teaching Physicians

The AASM supports the CMS proposal that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included. Medicare provides separate payment for the program's share of the resident's graduate medical training program, and we don't believe additional payment should be provided.

Billing for Physician Assistant (PA) Services (Section II.G.)

Given the amendment outlined in section 403 of the Consolidated Appropriations Act, which removes the requirement to make payment for PA services only to the employer of a PA effective January 1, 2022, the AASM supports the proposals to align with the CAA. These proposals allow for appropriate implementation of the amendment and do not change the reimbursement amounts or the requirement that PA services are performed under physician supervision.

Physician Self-Referral Updates (Section III.P.)

The AASM applauds the U.S. Department of Health and Human Services (HHS) and the CMS for continuing to attempt to address the burdensome impact of the physician self-referral law,

commonly known as the “Stark Law.” This proposed rule offers several helpful clarifications and definitions for terms such as indirect payment arrangements and units. However, the AASM reiterates the value of establishing exceptions for board-certified sleep medicine physicians who provide care for Medicare patients with OSA. Despite the Agency’s efforts to support value-based care, fee-for-service payment models are ongoing, and the proposals included in this rule do little to address the fragmented care experienced by most Medicare patients who have OSA, a chronic disease that afflicts about 30 million Americans, including an estimated 20-30% of the Medicare population.

Absent an exception that would allow sleep physicians to provide therapeutic durable medical equipment (DME) to Medicare patients directly for the treatment of OSA, the AASM would like clarification on the safe harbor to the Anti-Kickback Statute and the Physician Self-Referral Law (Stark) in the 2021 PFS final rule, "**Patient Engagement and Support**", which says, "To further support coordinated care, the Final Rule provides a safe harbor that allows providers to offer tools and supports to patients for the improvement of quality, outcomes and efficiency. The tools and supports may be provided by a value-based enterprise, as defined in the Final Rule, to a target patient population." Currently, DME providers are providing education to patients with OSA that receive positive airway pressure (PAP) therapy. However, sleep medicine physicians are fully trained and board-certified in sleep medicine and thus, are in a better position than DME suppliers to educate patients on the goals, benefits, and importance of adherence to treatment for patients that are prescribed positive airway pressure (PAP) therapy. The target population, in this case, is patients with OSA, and the tools and supports for patients leading to improved patient care, better patient outcomes, and efficacy of treatment are the patient education on PAP therapy that qualified board-certified sleep physicians can provide. As CMS turns to value-based health care, which is integrated, coordinated, patient-centered and multidisciplinary, the AASM, would again, like clarification of this safe harbor and whether it may be applicable to patients with OSA.

Summary of the Quality Payment Program Proposed Provisions (Section IV.)

Establishing the Performance Thresholds

The AASM strongly urges CMS to delay the increase in performance thresholds until the implementation of MVPs. As the PHE rages on, it will continue to be difficult for eligible clinicians and groups to meet performance thresholds, as they continue to provide high quality care to patients amidst lower patient volumes and higher operating costs. For the Agency to implement this change so soon, while also reimagining the entire MIPS program, would create even more burden for payers while negatively impacting payment adjustments, which most practices and clinicians cannot afford. We, instead encourage CMS to continue with the current performance threshold, which has proven difficult to meet amidst the PHE.

MIPS Value Pathway (MVP) and Alternative Payment Model (APM) Performance Pathway

The AASM understands the Agency’s intent to transition the MIPS program to more effectively

reward high-quality care for patients and increase opportunities for Advanced APM participation. **However, we are still uncertain of the level of involvement of medical specialties in the development of MVPs, and we encourage the Agency to reach out to relevant specialty societies to collect input from subject matter experts, to ensure that MVPs are constructed in a way that will positively impact value-based care.** This will also be helpful in ensuring that MVPs are available for all specialties, given the plan to completely sunset the MIPS program.

MVP Criteria

While the AASM understands the importance of demonstrating the feasibility and scientific acceptability of quality measures, there are significant levels of burden and cost associated with collecting required data and performing the appropriate data analyses for qualified clinical data registry (QCDR) measures. **We encourage CMS to extend the timeline for requiring fully tested QCDR measures within the MIPS program.** During the 2020 participation year, many individual clinicians and groups were grateful for the hardship exemption provided by CMS, as many practices have been turned upside down by the PHE and have not had adequate time or resources to dedicate to participation in the Quality Payment Program. While we agree that it has been less burdensome, and less costly, to provide face validity data initially, the cost of providing scientific acceptability data analyses to meet CMS requirements is yet an additional burden for practices that are struggling to stay afloat given the PHE. **We suggest that CMS further delay the requirement for full scientific acceptability testing until the year following the end of the PHE. In the meantime, we strongly urge CMS to consider continuing to accept face validity data for QCDR measures.**

MVP implementation timeline

We applaud CMS for the delay in MVP implementation until CY2023, given the recent surge of COVID-19 cases amidst the ongoing PHE, and we agree with the goal to gradually implement MVPs for eligible clinicians and groups. We also appreciate the Agency's consideration in making implementation voluntary for several years after what will hopefully be the end of the PHE, thereby, allowing eligible clinicians time to prepare their practices to participate.

Subgroup implementation timeline for MVP reporting

Subgroup implementation continues to be a point of confusion, as it is unclear what the benefit is of multispecialty groups being required to form subgroups to report MVPs. It is also unclear how a smaller subspecialty, like sleep medicine, will be factored into this requirement. Given that sleep medicine is a smaller subspecialty, it is not generally highlighted or specifically included in CMS legislation. Therefore, there is uncertainty about how this will impact our members, given that some members are only board-certified in sleep medicine while others are board-certified in sleep medicine as well as one or more additional specialties. Currently, CMS is proposing seven MVPs for the CY 2023 performance year, none of which are directly relevant to sleep medicine clinicians. **For smaller specialties that may not have relevant MVPs to report, we recommend that these specialties either be allowed to submit their own MVP for CMS consideration or that the**

Agency maintain the MIPS program for these clinicians. If ultimately the Agency decides to move forward with sunseting the MIPS program, we urge first testing MVPs, followed by close monitoring of MVP implementation to ensure program viability.

Data Collection Effort to Promote Health Equity

CMS is seeking comments on how to improve the collection and utility of data around health disparities that arise from social risk factors, including race and ethnicity. We applaud the Agency for considering health equity data collection initiatives to give providers a more comprehensive understanding of health disparities impacting their patients.

Data stratification by race and ethnicity

The AASM does not agree with the CMS methodology of implementing indirect estimation, using an algorithm to predict the race and ethnicity of beneficiaries based on other data sources. **Instead, we suggest allowing individual clinicians and groups that participate in national quality reporting programs like the Merit-based Incentive Payment System (MIPS or ultimately MIPS Value Pathways) to opt in to provide additional race and ethnicity data for this purpose. We also suggest CMS collect all social determinants of health data, including those defined by [Healthy People 2030](#):**

- Economic stability
- Education access and quality
- Healthcare access and quality
- Neighborhood and built environment
- Social and community context

The 5 domains listed above, coupled with race and ethnicity, will provide a more complete picture of factors impacting health equity. CMS may also consider reviewing existing social determinants of health data, which may have been previously collected by other Federal agencies.

Improving Demographic Data Collection

The AASM applauds the Agency's Quality Strategy, which includes a focus on building better data systems through data collection standards that enhance the agency's ability to identify health disparities. **Similar to the recommendation above, the AASM supports the implementation of data sharing or data use agreements that allows participants to opt in to share additional demographic data used in quality measures to help identify health disparities.** The AASM looks forward to future requests for information, in this regard.

Thank you for your consideration of these comments. The AASM appreciates the Agency's efforts to revise the Medicare Physician Fee Schedule in order to prioritize high quality clinical care for patients, while working to reduce administrative burden and navigate the challenges of the ongoing

public health emergency. We encourage the Agency to adopt the recommended changes summarized in this letter. 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,

Raman Malhotra, MD
AASM President

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