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September 5, 2022

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-1770-P. Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts

Submitted electronically via regulations.gov

Dear Administrator Brooks-LaSure:

The American Academy of Sleep Medicine (AASM) appreciates the opportunity to comment on the proposed rule for the 2023 Physician Fee Schedule (PFS) and Quality Payment Program since the proposed revisions will directly impact the care provided by AASM members to patients with sleep disorders and will also significantly affect physician reimbursements for these services, through the end of the current public health emergency (PHE) 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 facilities, providing sleep medicine services to the Medicare population.

The AASM strongly opposes the proposed \$1.53 decrease in the Medicare Conversion Factor, for Calendar Year 2023. While the AASM realizes that this Conversion Factor accounts for many factors, including the statutorily required update to the conversion factor for CY 2023, the expiration of the 3% increase in PFS payments for CY 2022 as required by the Protecting Medicare and American Farmers From Sequester Cuts Act, and the statutorily required budget neutrality adjustment of -1.55% to account for changes in Relative Value Units (RVUs), this reduction in the Conversion Factor will potentially lead to an approximate 4.42% percent reduction in physician payment, which will have grave consequences for physicians and their ability to continue providing high quality care to patients with sleep disorders. A 2021 survey completed by more than 230 members of the AASM showed that roughly 29% of those sleep medicine practices were concerned about remaining financially solvent through the end of the year due to the impact of the novel coronavirus. Although this survey was not conducted again in 2022, we can only imagine that the impact of the PHE continues to have long-lasting effects on health providers. At least 105 AASM-accredited sleep facilities have closed since 2020, and we anticipate an increase in the number of facility closures, as reimbursements continue to decline. The proposed additional payment reductions will further complicate recovery efforts, as providers continue navigating the already significant reductions in payment implemented over the last two years, while simultaneously navigating soaring prices due to record inflation, ongoing staffing shortages, and physician burnout, due to regulatory issues and administrative burden. The convergence of conversion factor reductions and looming statutory cutbacks, along with a 0% payment update, which fails to account for significant inflation in practice costs, will create long-term financial instability and unpredictability in the Medicare physician payment system, jeopardizing quality patient care. We urge CMS to work with Congressional leaders to once again, postpone sequestration cuts, and establish a higher Conversion Factor for the 2023 Calendar Year.

II.B. Determination of PE RVUs

Clinical Labor Pricing Update

The AASM has previously supported the Agency's goal to gather data to support updating the PFS direct Practice Expense (PE) inputs for supply and equipment pricing, while encouraging the Agency to develop an ongoing process and timeline to update pricing, going forward. The AASM also agrees that updating supply and equipment pricing will have a potentially negative impact on the allocation of direct PE, if the clinical labor pricing is not also subsequently updated and implemented in a similar manner. However, the increase in clinical labor pricing will largely impact the budget neutrality component within the PE RVUs for physician services with high-cost supplies and equipment, including diagnostic testing facilities. Therefore, while we support this effort, we encourage the Agency to a) establish an ongoing process and timeline for future updates, so the impact is not as great, in the future and b) inform Congressional leaders and representatives that the increases in clinical labor costs need to also be addressed through a positive update to the Medicare Conversion Factor.

II.C. Potentially Misvalued Services Under the PFS

None of the current codes identified as potentially misvalued are reported by sleep medicine providers. However, Medicare and other payers require standardized coding systems to process claims in an efficient manner. The Home Sleep Apnea Testing (HSAT) G-codes were added to the Healthcare Common Procedure Coding System (HCPCS) Level II codebook in 2008 to address the emergence of HSAT services. Three years later, the CPT Editorial Panel established category III codes and subsequently revisions and additions of category I CPT codes to report HSAT codes 95800, 95801, and 95806. The G-codes did not sunset with the establishment of the CPT codes as was intended, which has resulted in two separate procedure code sets for the same services. This redundancy in the coding system has led to inconsistences in HSAT claims processing across the nation and confusion amongst providers. Some Medicare Administrator Contractors (MACs) and commercial payers mandate the use of G-codes and do not accept CPT codes when reporting HSAT services while others will accept both CPT and G-codes. Not only does this system create confusion for administrative staff, but data collected from HSAT testing claims is divided among the two code sets, which detracts from the quality of research on service utilization. Given the establishment of the CPT codes, which are consistent with current technology and services provided for home sleep studies, we have no reason to believe the G codes remain relevant. We, therefore, encourage the Centers for Medicare and Medicaid Services to retire the G-codes G0398, G0399, and G0400. Removal of these codes would allow for greater standardization of service delivery for payers, providers, and patients.

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

Telephone E/M (Audio-only) Services

CMS noted that outside of the circumstances of the PHE, the telephone E/M services (99441 – 99443) would not be analogous to in-person care; nor would they be a substitute for a face-to-face encounter, and will, therefore, not be added to the Telehealth list. However, in most instances, if follow-up for an established patient is required and patients are unable to use audio/visual technology, it would be appropriate to use the audio-only codes, unless a physical exam is required. Additionally, providers have, historically, used their professional judgment to make decisions regarding whether they need to see a patient in-person and should be able to continue to do so in these instances as well. The AASM agrees that the audio-only codes should continue to be available for providers to furnish mental health services. However, we do not feel that this service should be limited to mental health services only. For instance, sleep medicine providers can access data from Continuous Positive Airway Pressure (CPAP) remotely and can use audio-only visits to briefly discuss ongoing symptoms, provide education regarding appropriate use of the device, and troubleshoot simple issues via telephone. 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). Therefore, we urge CMS to continue including the audio-only codes on the telehealth list, permanently, for all services that do not require a physical exam and can be provided without the visual component.

Emotional/Behavior Assessment Psychological or Neuropsychological Testing and Evaluation Services

CMS has proposed to temporarily include the Emotional/Behavior Assessment Psychological or Neuropsychological Testing and Evaluation Services codes on the Telehealth Services List, on a Category 3 basis, for the duration of the PHE. While the Agency has temporarily added the codes, there is still a question of whether high quality care can be provided to this patient population using telehealth. Again, the PHE has demonstrated the value of telehealth, particularly in those patients that have limited access to care. Therefore, we urge the Agency to finalize these codes as Category 2 codes, on a permanent basis, as we believe that there will be adequate data to support the continuation of these services as telehealth services, given the increased use amongst this patient population Finalizing these as Category 2 codes, will also ensure continued access to care for patients that are only able to access these services via telehealth.

Services Proposed for Removal from the Medicare Telehealth Services List After 151 Days Following the End of the PHE

For CY 2023, CMS is proposing to extend the duration of time that services will be temporarily available for the PHE for a period of 151 days following the end of the PHE. While the AASM appreciates the additional time included to allow providers a transition period after the telehealth PHE exceptions expire, we strongly suggest the Agency consider reviewing the data collected throughout the PHE to support the permanent addition of these services to the Telehealth list. Patients with sleep disorders have had increased access to care through telehealth visits, especially those in rural areas., Telehealth flexibilities have also improved road safety (patients who have excessive sleepiness can safely access care at home), eliminated travel for those that live at long distances from their provider(s), reduced reliance on caretakers, and reduced unnecessary exposures to illnesses (e.g., COVID-19, Influenza).

Use of Modifiers for Medicare Telehealth Services Following the End of the PHE for COVID-19

The AASM supports the CMS proposal to use Place of Service (POS) code 10 to indicate that the patient is at home at the time of a service. We also support the proposal to redefine POS 02 for locations other than the home. We agree that the definition for home (which is a location other than a hospital or other facility where the patient receives care in a private residence) when receiving health services or health related services through telecommunication technology is extremely helpful and inclusive. That said, it would be helpful to provide a more detailed

definition, or at least a few examples, for POS 02, to minimize confusion. We also encourage CMS to work with Congressional leaders to remove the restrictions on the patient location for all services, so POS 10 can be used for all Medicare telehealth services provided on or after the 152nd day after the end of the PHE. We also agree with using CPT Modifier 93 for the identification of audio-only services, to simplify billing for payers outside of Medicare.

The AASM encourages CMS to maintain payment for telehealth services through the end of the 2023 calendar year, at a minimum, regardless of when the PHE comes to an end. Significant cuts to telehealth reimbursement rates will not only increase concerns regarding access to care but may also disrupt continuity and quality of care for established patients.

Expiration of PHE Flexibilities for Direct Supervision Requirements

CMS is proposing to allow the PHE flexibilities for direct supervision to expire at the end of the PHE but is seeking comments on whether these flexibilities should be made permanent. The AASM continues to support making the PHE flexibilities for direct supervision requirements permanent, given the successes demonstrated throughout 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. We continue to maintain that in high-risk patients and specific scenarios (e.g., surgical procedures), in-person supervision is required. We also continue to support the creation of a potential modifier, which may help to easily identify services for which direct supervision through audio/visual telecommunications services may not be considered appropriate. Lastly, we strongly support requiring appropriate documentation, including the name of the resident and supervising physician, for all services that are supervised via audio/visual communications.

Valuation of Specific Codes (section II.E.)

Energy Based Repair of Nasal Valve Collapse (CPT Codes 37X01 and 30468)

Code	Long Descriptor	CMS Proposed Work RVU	RUC Recommended Work RVU
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)	2.80	2.80
37X01	Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling	2.44	2.70

Nocturnal nasal obstruction has been identified in a significant number of patients with obstructive sleep apnea and repair of nasal valve collapse is helpful in relieving sleep apnea symptoms. CMS proposed values for the newly created 37X01 code and 30468 code, which was recently reviewed

by the RUC. We agree with the CMS proposal to accept the RUC recommended work RVU and PE inputs for code 30468. However, we disagree with the CMS RVU recommendations and crosswalk for code 37X01. We would like to emphasize the importance of considering the components of physician time and the intensity for this particular service, as presented by the RUC, and recommend that CMS consider code 31295 as a more appropriate crosswalk, for the intensity of this code, and finalize the RUC recommended work RVU of 2.70.

Drug Induced Sleep Endoscopy (DISE) (CPT code 42975)

Code	Long Descriptor	CMS	RUC
		Proposed	Recommended
		Work RVU	Work RVU
42975	Drug induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep disordered breathing, flexible, diagnostic	1.58	1.95

The drug induced sleep endoscopy (DISE) code was created in 2020, initially valued at 1.90 work RVU by the American Medical Associated RBRVS Update Committee (RUC), on an interim basis, with a plan to resurvey. While CMS accepted this interim value, once the code was resurveyed using the 000-day global survey instrument, the RUC recommended a higher value of 1.95 work RVU. This is due to the 000-day global survey instrument not containing post operative visits, which CMS noted lowered the total time for physician work. The CMS recommended work RVU of 1.58 is not at all appropriate, as CMS has used a total time ratio methodology to determine what the agency considers a more appropriate work RVU. However, it is important to note that the interim value accepted by CMS in 2022 was based on inaccurate survey data, as the immediate post-service time was not captured appropriately in the initial survey of the code. Furthermore, the data submitted from 89 total otolaryngologists participating in the updated survey support the RUC recommended work RVU of 1.95. Therefore, the AASM strongly recommends that CMS rely on the updated survey data and RUC recommendations, rather than using the total time ratio, which neglects to capture the appropriate level of intensity of physician work and medical decision making required for this procedure.

Proposed Revisions to the "Incident to" Physicians' Services Regulation for Behavioral Health Services

CMS is proposing to amend the direct supervision requirement under the "incident to" regulation to allow behavioral health services to be furnished under the general supervision of a physician or non-physician practitioners (NPPs) when these services or supplies are provided by auxiliary personnel incident to the services of a physician or NPP. The AASM strongly supports this proposal as it is in accordance with the goal of the 2022 CMS Behavioral Health Strategy, to

improve access to and quality of mental health care services.

New Coding and Payment for General Behavioral Health Integration (BHI) billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs)

In the 2017 PFS Final Rule, CMS finalized that the same services that qualify as the initiating visit for Chronic Care Management would also qualify as initiating services for Behavioral Health Integration, which do not include in-depth psychological evaluation by a CP, and which were not, in their entirety, within the scope of CPs' practice, and therefore, CPs would not be able to report the General BHI code directly. We support the CMS proposal to create a new G code GBHI1 (Care management services for behavioral health conditions, at least 20 minutes of clinical psychologist or clinical social worker time, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales; behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes; facilitating and coordinating treatment such as psychotherapy, coordination with and/or referral to physicians and practitioners who are authorized by Medicare law to prescribe medications and furnish E/M services, counseling and/or psychiatric consultation; and continuity of care with a designated member of the care team.) describing General Behavioral Health Integration performed by CPs or CSWs, to account for monthly care integration where the mental health services furnished by a CP or CSW are serving as the focal point of care integration. The establishment of this code will help to address appropriate payment for behavioral health services while also addressing barriers in access to care for behavioral health patients. The establishment of this code will also help to recognize psychologists' role in integrated care and allow psychologists the flexibility required to support the behavioral health needs of the broader community. The AASM also believes that the proposed value for the code is appropriate, given the crosswalk to the care management services code, 99484.

Request for Information: Medicare Potentially Underutilized Services

The AASM applauds the CMS effort to seek comments on ways to identify specific services and to recognize possible barriers to improved access to high value, potentially underutilized services by Medicare beneficiaries. We are well aware of the factors that impede efficient and equitable care and are working to address those issues within the specialty and beyond, through the development of our own diversity, equity, and inclusion initiatives. However, we believe that CMS could do more in the way of providing appropriate payment for Psychology services. Given that a significant percentage of AASM members provide psychology services, in addition to sleep medicine services, we recommend that CMS consider establishing G codes to capture cognitive assessment & care without the inclusion of medication management, as medication is outside of the scope of the psychology license, in most states. Additionally, we suggest the establishment of G codes, to appropriately reimburse providers for Intensive Behavioral Therapy for Obesity

services. Providing reimbursement for these services will ensure that more patients have access and are able to receive appropriate treatment, in this regard.

II.F. Evaluation and Management (E/M) Visits

As participants in the AMA CPT and RUC processes, the AASM has remained engaged in ongoing updates to the E/M visits and related coding guidelines, approved by the AMA CPT Editorial Panel, for implementation in 2023. Therefore, we agree with the CMS proposal to adopt the majority of the changes made to coding and documentation for Other E/M visits.

Prolonged Services

While the AASM understands that CMS may be hesitant to implement the revised CPT prolonged service framework, as proposed, we urge the Agency to continue to engage with the CPT/RUC Workgroup on E/M to harmonize the prolonged services policies for 2023 to minimize confusion and administrative burden, in the future.

Split or Shared Visits

CMS has proposed to delay the requirement that only the physician or qualified health professional (QHP) who spends more than half of the total time with the patient during a split or shared visit can bill for the visit, until 2024. The AASM strongly supports this proposal and encourages CMS to allow physicians or QHPs to bill split or shared visits based on time or medical decision-making. The AASM, along with over 40 other medical specialty societies signed onto an AMA letter, submitted to CMS earlier this year, which highlighted concerns about implementation, including an emphasis on potential disruption to team-based care and the potential negative impact on the care delivery model in the facility setting. We are reiterating those concerns here, as well.

II.I Non-Face-to-Face/Remote Therapeutic Monitoring (RTM) Services

The AASM continues to support the implementation of the remote physiologic monitoring and remote therapeutic monitoring codes, so remote services can be provided to patients with sleep disorders. However, we are concerned about some of the limitations placed upon the code set, as well as the proposal of the four new G codes.

With regard to the limitations, we encourage the Agency to recognize the value in these codes being applied to multiple specialties and subspecialties, including sleep medicine, as the existing supply codes are limited to musculoskeletal and respiratory services. While the AASM is excited that CMS has added cognitive behavioral therapy (CBT) to the family of RTM services, and agree with contract pricing for the code, we feel that the omission of the new CBT supply code (989X6) implies that CMS will not allow behavioral therapy providers to bill work performed in support of CBT services. This will lead to the unintended consequence of a lack of services for behavioral

therapy patients that would potentially benefit from remote therapeutic monitoring while receiving treatment.

The Agency has requested information regarding types of data collected using RTM devices, including information about how the data that are collected solve specific health conditions, episodes of care, etc. Respiratory Assist Devices and Positive Airway Pressure (PAP) therapy devices (E0470, E0471, and E0601) are commonly used remote monitoring devices in sleep medicine, for the treatment of Obstructive Sleep Apnea (OSA). Episodes of care for sleep apnea vary and data are collected remotely, several times throughout each month, to allow providers to review efficacy and recommend adjustments.

Additionally, the AASM disagrees with the addition of the four new G codes, proposed by CMS. The creation of two G codes for the purposes of documenting the type of clinical staff providing a service seems unnecessary. The proposed G codes also do not include direct PE clinical staff time and will create additional unnecessary administrative burden for providers. The other two proposed G codes seem to be identical to CPT codes 98980 and 98981, and even include the same amounts of physician work and direct PE inputs, which makes them redundant. CMS should consider allowing for general supervision, to avoid the necessity of such a code.

Current Medicare Economic Index (MEI) weights were established using data obtained from a 2007/2008 AMA Physician Practice Information (PPI) Survey. Although the AMA is in the process of obtaining updated data in this regard, CMS is proposing to update the MEI weights using 2017 data from the US Census Bureau's Service Annual Survey (SAS), with implementation in 2023. The SAS for physician offices collects payroll and benefits for all staff combined, but the MEI has separate cost categories for physician and non-physician compensation. To that point, CMS appears to have misclassified some health care professionals' salaries in their estimates and the Occupational Employment and Wage Statistics data only covers employees, so it does not include compensation for a large segment of the physician population (practice owners). Conversely, the AMA has since shared that they have contracted with another organization to develop a sampling method and a design methodology to survey financial experts at physician practices to collect practice cost data at the specialty level, with reports ready for review toward the end of 2022. Given the Agency's reliance on AMA physician cost data in establishing previous MEI weights in the past, coupled with the ongoing collaboration with the RUC, we suggest that CMS work with the AMA and all other national medical specialty society organizations to update the MEI weights. Given the delay in implementation, the AMA data collection effort would conclude in a timely manner. The AASM would also welcome any opportunity to participate in ongoing data collection efforts.

IV.A. CY 2023 Modifications to the Quality Payment Program

MVP Development

After reviewing the MIPS Value Pathways (MVPs) available for 2023 implementation, the AASM would like to stress the importance of input from subject matter experts, clinicians, and other valuable stakeholders in the development of future MVPs. While we agree with the modification to the MVP development process, in that draft versions of all MVPs should be posted for a 30-day public comment period, similar to quality measure development methodologies, we request clarification on the CMS language that states the MVPs will be posted when CMS determines that they are "ready" for feedback. It should be clarified whether any preliminary feedback would be provided to the interested party, submitting the MVP, requesting updates or revisions if an MVP is not determined to be "ready" for public comment. Additionally, it's not clear why CMS would not notify the interested party that submitted the MVP if the Agency determines that changes are needed after the public comment period. Alerting the interested party and allowing them to make changes in advance of the rulemaking process would save time, allowing an updated version to be included in the rules for additional comment.

MVP Maintenance Process and Engagement with Interested Parties

The AASM agrees with the idea of holding a public-facing webinar, open to interested parties and the general public, to offer feedback on potential revisions to MVPs. This will give more stakeholders the opportunity to weigh in on draft MVPs prior to finalization. However, we also recommend that the Agency reach out to relevant stakeholders, for peer review, given relevant topics. For example, during the AASM measure development/maintenance process, we post quality measures for public comment, but we also reach out to relevant stakeholders (i.e., other medical specialty societies) that we know will have input, to ensure that they are aware of the opportunity to comment, since we know the quality measures will be utilized by members of their organization. We recommend CMS take this approach, when possible.

Proposed New MVPs

We agree with the Agency's goal to gradually develop MVPs that are relevant and meaningful to all clinicians who participate in MIPS. However, we strongly suggest that the Agency hold an annual Call for Measures, as we understand that the ultimate goal is to sunset the MIPS program and focus on MVP implementation, otherwise, MVPs that would be relevant and meaningful to small specialties/subspecialties, like sleep medicine, would not be prioritized.

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. 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,

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 American Academy of Sleep Medicine. (2021, April). COVID-19 Pulse Survey.[PowerPoint slides]. https://aasm.org/covid-19-resources/coronavirus-pulse-survey-sleep/