

October 5, 2020

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Updates to the Quality Payment Program; Medicare Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Proposal to Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy Proposed Rule

Dear Administrator Verma:

The American Academy of Sleep Medicine (AASM) appreciates the opportunity to comment on the proposed rule for the 2021 Physician Fee Schedule and Quality Payment Program, as the proposed revisions will directly impact AASM member participation and reimbursements, during the public health emergency and beyond. The comments included in this response reflect the needs of our over 9,000 individual members and 2,500 accredited sleep centers, providing sleep medicine services to the Medicare population.

The AASM strongly opposes the proposed significant decrease in the Medicare conversion factor, due to budget neutrality. The significant reduction in the conversion factor, which is \$3.83 below the CY 2020 PFS conversion factor, will potentially lead to an approximate 11 percent reduction in physician payment, which will have grave consequences to physicians and their ability to provide high quality care to patients. A recent survey completed by more than 500 members of the AASM showed that roughly 46% of those sleep medicine practices are concerned about remaining financially solvent through the end of the year due to the impact of the novel coronavirus¹. We have heard from

colleagues in other specialties that they have similar concerns due to lower patient volumes, limited access to personal protective equipment, and concerns about mitigation strategies in many areas across the country. It is well known that the impact of the public health emergency (PHE) has already had long-lasting effects on the United States health care system and this will be another devastating blow for providers. Therefore, we stand with the American Medical Association (AMA), along with over 170 other medical specialties, in strongly urging Centers for Medicare & Medicaid Services (CMS) to use its authority to waive budget neutrality and to increase physician payment, as previously finalized, for the E/M office/outpatient visits.

Provisions of the Proposed Rule for the PFS

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

In the CY 2021 Proposed Rule, the CMS is proposing to add all codes included in Table 8 to the Medicare Telehealth Services List on a Category 1 basis. Overall, the AASM supports the efforts of CMS to extend the telehealth services list by adding codes that are similar to services currently on the list. However, the AASM recommends that code GPC1X be referred to the AMA Current Procedural Terminology (CPT) editorial panel, as we believe the CPT Panel review would aid in further refining the reporting instructions for the add-on code, making appropriateness of reporting more clear. Without additional clarification, it may not be apparent when it is appropriate to report the code, despite it being added to the Medicare Telehealth Services list.

Adding Services to the Medicare Telehealth Services List

The AASM fully supports the Agency's proposal to create a Category 3 in the Medicare Telehealth Services list. New technologies are consistently being created and used to advance healthcare, which is an indication that there will continue to be opportunities for CMS to add services to Category 3 in the future. We, therefore, support implementing Category 3 through the end of the calendar year in which the COVID-19 PHE ends but strongly propose that CMS consider making Category 3 permanent.

Communication Technology-Based Services (CTBS)

The AASM has fully supported the finalization of separate payment for HCPCS codes G2061 (*Qualified nonphysician healthcare professional online assessment and management, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*), G2062 (*Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*), and G2063 (*Qualified nonphysician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more*

minutes) for nonphysician practitioners. We, therefore, also support the Agency's decision to finalize, on an interim basis for the duration of the PHE for the COVID-19 pandemic, that these services could

be billed for example, by licensed clinical social workers, clinical psychologists, and other therapists who bill Medicare directly for their services when the service furnished falls within the scope of these practitioner's benefit categories. The AASM fully supports the Agency's proposal to adopt this policy on a permanent basis, allowing nonphysician practitioners to continue to bill for these services.

The AASM also supports the finalization of G20X0 (*Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.*) and G20X2 (*Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot 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 a service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion*), which can be billed by practitioners who cannot independently bill for E/M services. We also agree that these codes should be valued identically to G2010 and G2012, as the services are similar and no additional clinical staff time, equipment or supplies will be required to provide this service. However, the AASM strongly disagrees with the designation of G20X0, G20X2, G2061, G2062, and G2063 as "sometimes therapy" services, as this designation will very likely lead to confusion as to when they are appropriate to report. On the other hand, the clarification that these CTBS can be documented by auxiliary staff under general supervision, as well as by the billing practitioner, is extremely helpful.

Comment Solicitation on Continuation of Payment for Audio-only Visits

The Agency has indicated that it is not able to waive the requirements that telehealth services be furnished using an interactive telecommunications system that includes two-way, audio/video communication technology, yet recognizes the need for audio-only communication, via discussions that are longer than those that would be captured by the virtual check-in codes. Since the Agency is unable to permanently waive the requirement that two-way, audio/video communication technology be used for telehealth services, the AASM strongly supports developing coding and payment for audio-only services similar to the virtual check-in, with longer units of time, parallel to the units of time associated with E/M visits, so providers are able to accurately report time, as they are able to do during the PHE, using codes 99441- 99443. Payment for the new audio-only codes should also align with the reimbursement received for 99441 – 99443, as finalized during the PHE. The AASM also believes the establishment of these new codes should be a permanent PFS payment policy, as allowing providers to report these services will lead to continued, increased access to care for patients, especially those patients that do not have access to audio/video technology and/or those that are not as experienced with this technology. The establishment and implementation of these codes will also lead to increased patient engagement, as costs for patients would significantly decrease, and greatly reduce the number of patients potentially lost to follow-up going forward.

Comment Solicitation on Coding and Payment for Virtual Services

The AASM appreciates CMS efforts to identify additional ways to reimburse for an expanded list of virtual services. Clinician experiences with using virtual services during the PHE will provide important insights as to how CMS should move forward in this area. Therefore, the AASM suggests that CMS include both existing and new Communication Technology-Based Services (CTBS) in Category 3 Medicare Telehealth Services, as these services are similar to face-to-face services, as noted in the criteria. Limiting CTBS to inherently non-face-to-face services restricts the many ways care and services may be provided to patients.

Proposed Clarification of Existing PFS Policies for Telehealth Services

The AASM appreciates the Agency's efforts to clarify existing policies for telehealth services. We absolutely agree that the existing definition of direct supervision makes it difficult for a billing clinician to provide direct supervision of services provided via telehealth incident to their professional services by auxiliary personnel. The AASM, therefore, supports the proposed amendment to the definition of direct supervision, to permit virtual presence. This amendment will make it clear that services provided incident to the professional services of an eligible distant site physician or practitioner may be reported when direct supervision requirements are met at both the originating and distant site through virtual presence of the billing physician or practitioner.

Direct Supervision by Interactive Telecommunications Technology

Revising the definition of direct supervision to allow for the virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology has been extremely helpful in allowing physicians to supervise other clinical staff without having to be physically present, effectively reducing the potential infection risk to both patients and healthcare personnel. The policy has also provided additional flexibility for all parties involved, allowing the supervising physician to be available to multiple clinical staff for supervision and allowing for a higher volume of patient visits. Therefore, while AASM appreciates the Agency's efforts to maintain this policy until the later of the end of the calendar year in which the PHE ends or December 31, 2021, we encourage CMS to make this policy permanent for outpatient services and procedures. We realize that the policy may not be appropriate to make permanent for high risk procedures and/or complex patient populations, which may require in-person supervision, and, therefore, suggest CMS develop a list of high risk procedures and complex patient populations for whom this policy may not be appropriate, if made permanent.

Remote Physiologic Monitoring (RPM) Services

The AASM appreciates the clarifications regarding appropriateness of reporting the remote physiologic monitoring (RPM) codes and who can furnish these services. Sleep medicine professionals have been reluctant to report 99453, 99454, 99457, 99458, and 99091, due to confusion regarding the parameters, and have taken a rather conservative approach to reporting these codes to date. The

additional clarifications have answered many outstanding questions and will help clinicians feel more comfortable reporting, as appropriate.

The AASM fully supports the CMS proposal that consent for RPM services be obtained at the time that these services are furnished. However, the AASM suggests that the Agency clarify whether an annual consent is acceptable for these codes, as it is for virtual check-ins. The AASM also strongly supports the CMS proposal to allow auxiliary personnel to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner. However, we encourage CMS to consider allowing RPM services to be furnished to both new and established patients on a permanent basis, as long as any information necessary for a new patient visit or initial follow-up visit can be obtained through the patient's history and a copy of the patient's medical record. The AASM agrees that the flexibilities implemented for RPM codes should remain in place and be extended to at least one year beyond the end of the pandemic.

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID-19 Pandemic

CMS is proposing to implement the actual total times, which are the sum of the component times, rather than the total times recommended by the RUC for CPT codes 99202 through 99215. While the AASM understands that the total time is usually a sum of the pre-, intra- and immediate post-service time, we would like to reiterate that physician time was captured differently for the office visits survey, which led to great variability in survey responses. However, the total times were the same and the work is the same regardless of the dates performed. The median total time, recommended by RUC, take into account the variability in the components. Therefore, we support the RUC recommended median total time and strongly urge CMS to use the RUC recommended medial total time in lieu of the sum of the component times, as proposed.

Therapy Evaluations

As sleep medicine is considered a sub-specialty, many AASM members are board-certified in multiple specialties, while others are dentists, sleep psychologists, sleep technologists, respiratory therapists, advanced practice providers, etc. On behalf of our sleep psychologist members, the AASM strongly supports the Agency's proposal to adjust the work RVUs for therapy services. However, we urge the Agency to ensure that new work RVUs are resource-based, which may be accomplished by uniformly applying the office visit increases across services/specialties to reflect the value of the office/outpatient E/M visits. As participants in the RUC process, we strongly oppose the practice of attempting to increase the value of the codes by applying other calculation methodologies (i.e., applying an arbitrary 28% increase).

Behavioral Healthcare Services

As with the therapy evaluations, the AASM also agrees that there should be an increase in the values for standalone therapy services to reflect the value of the office/outpatient E/M visits. The AASM again urges CMS to apply the office visit increases uniformly, rather than increasing payment based

on other calculation methodologies.

Comment Solicitation on the Definition of HCPCS code GPC1X

While we agree with the importance of the provision of comprehensive and longitudinal care, the AASM agrees with others that have previously shared feedback regarding the definition of this service that it remains unclear. Clarifications to the definition and the code-descriptor will help to determine appropriateness of reporting and would also assist with utilization assumptions. If the intent of this code is to capture the provision of more patient-centered care, it would be helpful to provide very specific examples/clinical scenarios for when reporting would be most appropriate. It would also be helpful to share details regarding whether the intent is for the code to be reported with any/all office visit codes (i.e., if a physician discusses shared decision making around therapeutic goals, regardless of the level of the visit, they would report GPC1X).

Scope of Practice and Related Issues

The AASM agrees that physicians, non-physician practitioners (NPPs), and other professionals should be able to furnish services to Medicare beneficiaries in accordance with their scope of practice and state licensure, for the majority of patients. However, while we continue to support this opportunity for alignment with state licensure, we are concerned with the safety of more complicated, high-risk patients. As there are some states that require supervision and others that require collaboration, the AASM encourages CMS to ensure that services are not provided to complicated, high risk patients independent of physician oversight. AASM recommends that CMS specify that services are provided with physician collaboration or under appropriate supervision, per state laws.

Teaching Physician and Resident Moonlighting Policies

The AASM applauds the CMS policy, which states that during the COVID-19 public health emergency, services of residents that are not related to their approved GME programs and are separately billable for payment under the Physician Fee Schedule will be compensated. The AASM fully supports residents being able to participate in moonlighting, while in good standing with their individual programs, as long as the activities are complicit with standards of the Accreditation Council for Graduate Medical Education (ACGME) standards and patient safety is prioritized. The AASM strongly urges CMS to make this policy of allowing moonlighting permanent, going forward, beyond the PHE.

Supervision of Residents in Teaching Settings through Audio/Video Real-Time

The AASM, again, applauds the Agency's efforts in allowing supervision of residents in teaching settings through audio/video real time, throughout the pandemic. We note that while this policy has limited potential opportunities for exposure to the novel coronavirus, it has also allowed more flexibility to residents as they have been able to receive feedback in a more timely manner, while managing other tasks and providing additional services. We, therefore, strongly support this policy being made permanent, allowing supervision through interactive telecommunications technology. As

individual programs determine the appropriateness of implementing this practice, on a case-by-case basis, and ensure the appropriate technology is in place, we feel that this policy will be effective in allowing more flexibility to clinicians, as they provide high quality care.

Virtual Teaching Physician Presence during Medicare Telehealth Services

Virtual teaching has been an extremely helpful tool through the PHE, and has allowed programs to expand their teaching presence, especially in rural and underserved areas. The policy has also allowed increased training opportunities and has increased patient access to care. Given the successful implementation of this policy throughout the PHE, the AASM strongly urges CMS to make this policy permanent.

Quality Payment Program

Candidate MVP Co-Development, Solicitation Process, and Evaluation

The AASM agrees with CMS that there must be a process to ensure stakeholder engagement and collaboration in the development of MIPS Value Pathways (MVPs). While we also agree that there must be a streamlined process for the Agency to receive and evaluate candidate MVPs, it is unclear if there will be an opportunity for public comment on the proposed MVPs, once they are published in the QPP Resource Library. If not, we are unclear as to why they would be published there, prior to CMS approval. Additionally, while the AASM thinks a Call for MVPs would be appropriate, similar to the Call for Measures, we strongly urge the Agency not to emulate the NQF convened pre rulemaking process, given the lack of transparency and potential for delayed implementation of the MVPs.

Incorporating Qualified Clinical Data Registry (QCDR) measures into MVPs

The AASM is excited about the possibility of incorporating Qualified Clinical Data Registry (QCDR) measures into MVPs, as including these measures will enable sleep medicine professionals to report on measures that are clinically relevant. We also believe that incorporating QCDR measures into MVPs will encourage eligible clinicians to report on measures developed by other stewards, as appropriate, rather than focusing primarily on the measures stewarded by their own specialty. We agree with the CMS proposal to allow QCDRs and qualified registries to identify and select which MVPs they can support following the publication of the final rule. This mirrors part of the current self-nomination process in which applicants select which MIPS measures, promoting interoperability measures and improvement activities they will be able to support for the next performance year.

Timeline for MVP implementation

We applaud CMS for delaying MVP implementation, given the PHE, and we agree with the goal to gradually implement MVPs for eligible clinicians and groups over time. However, the AASM encourages CMS to delay implementation until at least the 2023 performance period, as we are not yet clear on the long-lasting effects of the PHE.

QCDRs: Measure Testing Requirements

The AASM applauds CMS for the proposal to modify the QCDR measure testing policy. While we certainly understand the importance of demonstrating the feasibility and scientific acceptability of quality measures, there is a significant level of burden and cost associated with collecting the required data and performing the appropriate data analyses, especially for specialties with newly established QCDRs. We are supportive of the gradual approach to have fully tested QCDR measures within the MIPS program and believe that it will be less burdensome, and less costly, to provide face validity data initially, which will give measure stewards time to collect data and perform data analyses to meet the requirements for measures to be fully tested for subsequent years. However, if CMS will require at least one year of data for analysis, only allowing face validity for one year will not allow measure stewards time to query and analyze the data in time for the self-nomination period. Therefore, we strongly urge CMS to consider allowing face validity data for the first two performance years that measures are designated QCDR measures.

Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020

The AASM applauds CMS for providing flexibility for eligible clinicians and groups by implementing the MIPS Extreme and Uncontrollable Circumstances Hardship Exemption policies. This flexibility has been particularly helpful throughout the PHE and has relieved some of the administrative burden placed upon physicians, while working on the frontlines to treat patients and minimize the spread of the novel coronavirus. While the PHE has been extended until October 23, 2020, we are not yet aware if there will be an opportunity to return to business as usual at any point in the near future. As we are not yet clear on the potential long-term impacts from the PHE, we suggest CMS extend the exemption through the end of 2021 or the end of one year following the end of the PHE.

Topped-Out Measures

Per comments from previous years, the AASM still does not support the removal of measures based solely on the benchmarking data without CMS demonstrating that the clinicians reporting on the measures are a nationally representative sample. While AASM understands that CMS intends to reduce administrative and data collection burden while ensuring that measures included in the Quality Payment Program provide value to clinicians and patients, we still feel it may be helpful for CMS to request supplemental data from a specialty, to substantiate continued inclusion in the program, particularly in the instance that a specialty is collecting their own specialty-specific measure performance data. The AASM, once again, urges CMS to consider options for specialties that are limited in reporting options and/or whose applicable measures, which may be topped out, are not included in a QCDR accessible by that specialty. Smaller specialties are limited in their ability to participate in the Quality Payment Program, and we encourage CMS to make participation easier or to provide an exemption if there are few or no measures available for specific groups of specialists to report.

TABLE Group B: New Specialty Measures Sets and Modifications to Previously Finalized Specialty Measure Sets Finalized for the 2023 MIPS Payment Year and Future Years

The AASM fully supports the CMS proposal to include measures 277 – Sleep apnea: Severity assessment at initial diagnosis and 279 – Sleep apnea: Assessment of Adherence to Positive Airway Pressure Therapy to the Neurology specialty set. Inclusion in the Neurology set may lead to increased reporting of these measures and more robust data on sleep apnea diagnosis and treatment. We also support the continued inclusion of these measures in the Internal Medicine, Pulmonology, and Otolaryngology specialty sets. Many board-certified sleep medicine physicians are also board-certified in other specialties and will benefit from the inclusion of these measures in these specialty sets.

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 clinical care for patients, while continuously working to reduce administrative burden and navigate the challenges of the public health emergency. We encourage the Agency to adopt the 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,

Kannan Ramar, MD
AASM President

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

ⁱ Ramar K. (2020). AASM takes the pulse of the sleep field and responds to COVID-19. *Journal of Clinical Sleep Medicine*. Advance online publication. <https://doi.org/10.5664/jcsm.8846>