October 5, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: **CMS-1734-P**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1734-P; CY 2021 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (August 17, 2020)

Dear Administrator Verma,

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 6,200 physicians and associated health professionals who specialize in the prevention and treatment of addiction, thank you for the opportunity to provide comments on the proposed revisions to Medicare payment policies under the Physician Payment Schedule for calendar year (CY) 2021. Many of its proposed policies will have a significant impact on our members and the patients we serve.

II. D Telehealth and Other Services Involving Communications Technology

CY 2021 Proposed Additions to the Medicare Telehealth Services List on a Category 1 Basis

ASAM supports the addition of the following codes to the Medicare Telehealth Services List on a Category 1 basis: HCPCS 90853 (Group psychotherapy) and HCPCS 99334, 99335, 99347, and 99348 (Domiciliary/home visit for E/M of established patient), the latter of which could only be billed when furnished as telehealth services only for treatment of a substance use disorder (SUD) or co-occurring mental health disorder. While the patient's home cannot serve as an originating site for purposes of most Medicare telehealth services, the SUPPORT for Patients and Communities Act removed geographic limitations and authorized the patient's home to serve as a telehealth originating site for purposes of treatment of an SUD or a co-occurring mental health disorder, furnished on or

after July 1, 2019, to an individual with a substance use disorder diagnosis. These domiciliary/home visits contain the same elements and similar descriptors to the office/outpatient E/M visits, and therefore, we agree with CMS that there is sufficient justification to add them to the Medicare telehealth services list on a Category 1 basis.

Proposed Temporary Addition of a Category 3 Basis for Adding to or Deleting Services From the Medicare Telehealth Services List

ASAM appreciates the creation of a temporary, third category of criteria for adding services to the Medicare telehealth services list to describe services that would be included on the Medicare telehealth services list on a temporary basis. This approach will allow CMS to collection information about the use of various telehealth services during the COVID-10 Public Health Emergency (PHE), and it will allow for uninterrupted care for patients while data are gathered to support the permanent inclusion of such services on the Medicare Telehealth Services list under Category 1 or Category 2 criteria. ASAM supports the inclusion of Neuropsychological and Psychological Testing codes (HCPCS 96130, 96131, 96132, and 96133) as temporary additions to the Medicare Telehealth Services List under Category 3 criteria, with the understanding that they will remain on the list through the calendar year in which the PHE ends.

Continuation of Payment for Audio-only Visits

During the PHE, audio-only telephone evaluation and management (E/M) services have been a vital linkage to care for many patients with substance use disorder. These services have been especially beneficial for patients in rural areas who may not have access to reliable internet service, which limits their ability to access two-way, audio-video communication technology. They have also been lifelines to patients leaving incarceration and reentering the community, who often do not have access to two-way, audio-video communication technology. Because challenges with reaching these vulnerable populations will remain after the conclusion of the PHE for the COVID-19 pandemic, **ASAM encourages CMS to develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value.** ASAM recommends CMS pay for this service at parity with face-to-face E/M services using 2021 values.

Moreover, we recognize that, outside of the circumstances of the PHE, CMS does not have the flexibility to waive the requirement that telehealth services be furnished via two-way, audio-video communication technology. However, CMS does have the statutory authority to change the audio-visual requirement through the regular notice and comment rulemaking process. ASAM supports legislation, the Telehealth Response for E-prescribing Addiction Therapy Services (TREATS) Act, that makes explicit Congressional understanding that nothing shall preclude the furnishing of telehealth services through audio- or telephone-only technologies in the case where a physician or practitioner has already conducted an in-person medical evaluation or a telehealth evaluation that utilizes both audio and visual capabilities with the eligible telehealth individual. ASAM encourages CMS to revise its telehealth definition via regular notice and comment rulemaking to allow for payment for audio-only visits to eligible telehealth

individuals with an SUD diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder.

II.F. 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

Bundled Payments under the PFS for Substance Use Disorders (HCPCS codes G2086, G2087, and G2088)

Conceptually, ASAM supports CMS's proposal to expand these bundled payments to be inclusive of all SUDs. Generally speaking, treatment initiation for any SUD requires "intake activities and development of a treatment plan, as well as assessments to aid in development of the treatment plan in addition to care coordination, individual therapy, group therapy, and counseling" (HCPCS G2086) and ongoing treatment requires monthly "care coordination, individual therapy, group therapy, and counseling" (HCPCS G2087). However, ASAM notes that this change presents some coding and payment challenges.

First, expanding the use of these codes to all SUD diagnoses may present the opportunity for fraudulent, duplicative coding, were providers to bill the codes for each SUD diagnosis. Many patients with SUD use multiple substances and require treatment for more than one substance. ASAM recommends that CMS limit billing of these codes to once per month per patient.

With that in mind, ASAM notes that SUD presents on a spectrum of severity from mild to severe use disorder, and that the complexity of treatment planning and intensity of ongoing care coordination, therapy and counseling varies accordingly. Thus, ASAM recommends CMS stratify payment for these codes based on disease severity and complexity (e.g., as demonstrated by medical and pharmacy claims indicating single vs. polysubstance use disorder, co-occurring and potentially complicating mental or physical health conditions, etc.) Ideally, this stratification should be based on the results of a multidimensional, biopsychosocial assessment such as that described by *The ASAM Criteria*. Such a reconceptualization and specification of these codes requires more in-depth conversations among CMS and relevant stakeholders. **ASAM respectfully requests to meet with CMS to discuss how these codes can be stratified to reflect disease severity and more clearly described in future years.**

Initiation of Medication Assisted Treatment (MAT) in the Emergency Department (HCPCS code GMAT1)

ASAM supports the creation of an add-on G-code to be billed with E/M visit codes used in the ED setting to pay for assessment, referral to ongoing care, follow-up after treatment begins, and arranging access to supportive services. The ED can be an important entry point to SUD treatment, but only if treatment can be timely initiated when patients are ready to start, as is often the case when they present to the ED. Warm hand-offs from the ED to community based treatment are necessary to facilitate ongoing care. We know ED clinicians are already doing this work, but do not yet have a standardized way to bill for these services. This new code will be

helpful to ensure consistency in billing, proper reimbursement, and clear incentives for ED clinicians to initiate medication treatment and follow up with patients after referring them to ongoing care.

II.I. Modifications related to Medicare Coverage for Opioid Use Disorder (OUD) Services Furnished by Opioid Treatment Programs (OTPs)

Definition of OUD Treatment Services

CMS has proposed amending the definition of OUD treatment services at § 410.67(b) to include opioid antagonist medications that are approved by the Food and Drug Administration for the emergency treatment of known or suspected opioid overdose. Accordingly, CMS has proposed the creation of two new add-on codes, HCPCS code GOTP1 and HCPCS code GOTP2, to reimburse OTPs for providing naloxone to patients. GOTP1 will reimburse OTPs for providing a take-home supply of nasal naloxone; GOTP2 will reimburse OTPs for providing a take-home supply of auto-injector naloxone. **ASAM supports the creation of these two new codes**, as well as the pricing methodology used to value them. Additionally, **ASAM encourages CMS to establish a code to reimburse OTPs for providing a take-home supply of injectable naloxone to patients**. ASAM notes that injectable naloxone has been shown, in some cases, to reverse the effects of an overdose more rapidly than nasal naloxone, and it may be more effective for overdoses due to potent synthetic opioids such as fentanyl. Furthermore, there may be regional and patient preferences for the various delivery methods of naloxone.

CMS proposes to limit payment to OTPs for naloxone to one add-on code (GOTP1 or GOTP2) every 30 days. ASAM appreciates the rationale CMS has used to inform this limit, but we **recommend that exceptions be made for patients with a recent (<30 days) overdose and those with a recent transition in level of care.** With the evolving supply of increasingly potent opioids, ASAM recommends CMS regularly evaluate the appropriate dosage and number of units of naloxone covered.

CMS has additionally requested input on whether it should further alter the definition of OUD treatment services to include community education related to overdose prevention. It is considering reimbursing OTPs for providing overdose education to a beneficiary and their partner or family by creating an add-on code similar in value to CPT code 96161. **ASAM supports CMS reimbursing OTPs for providing overdose education. Since all patients receiving treatment at an OTP as well as their families should receive this education, ASAM urges CMS to include this payment in the add-on payments for intake activities and periodic assessments, which would indicate a possible transition in care, and increase the current payment rate accordingly to account for universal provision of these services at intake and care transitions. ASAM also urges CMS to include overdose education in the bundled payment for the initial month of substance use disorder treatment (HCPCS code G2086) and similarly increase payment for this code to reflect the provision of this service to all patients.** This will ensure that all those receiving treatment for OUD and their families receive this necessary education.

Billing and Payment Policies

Finally, CMS has proposed revising § 410.67(b)(7) to allow periodic assessments, which it proposes to define as limited to a face-to-face encounter, to be furnished via two-way, interactive audio-video communication technology, provided all other applicable requirements are met. ASAM supports this revision to help to expand access to care for patients who may have a difficult time getting to the OTP in person.

CMS goes on to note that, during the PHE for the COVID-19 pandemic, it has allowed periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, recognizing that not all beneficiaries receiving OUD treatment services from OTPs may have access to interactive audio-video communication technology. This limitation in access to audio-video communication technology will not end with the COVID-19 pandemic, however, and continued payment for audio-only periodic assessments may be necessary to ensure continued access to care for some patients.

III.K. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a prescription drug plan or an MA-PD plan (section

Section 2003 of the SUPPORT Act generally mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021. Given the difficulties that the COVID-19 PHE has presented to medical practices that are working to adopt EPCS, ASAM supports CMS's proposal to require EPCS for Schedule II, III, IV, and V controlled substances using the NCPDP SCRIPT 2017071 standard by January 1, 2022 instead of 2021.

N. Proposal to Establish New Code Categories

ASAM understands that CMS has received feedback from stakeholders that there is variability in bioequivalence between the buprenorphine/naloxone products within the range of strengths described by the four existing HCPCS Level II codes, meaning that products within a current code are not necessarily substitutes for one another, that is, they are not therapeutically equivalent. To facilitate more accurate coding and more specific reporting of the variety of buprenorphine/naloxone products on the market, CMS is proposing an expanded series of 15 new code categories to report all currently marketed buprenorphine/naloxone products, based on strength as well as therapeutic equivalence. ASAM is concerned this change overly complicates billing and coding for buprenorphine/naloxone products and adds complexity to clinician workload without clear or substantive benefit to patients. ASAM does not recommend CMS finalize this proposed change and instead recommends the four existing codes remain in place.

Thank you again for the opportunity to provide comments on this important proposed rule. Please contact Susan Awad, Director, Public Policy and Regulatory Affairs at sawad@asam.org or 301-547-4106 with any questions about our comments. We look forward to continuing to work with CMS to expand access to evidence-based addiction treatment services.

Sincerely,

Paul Earley, MD, DFASAM
President, American Society of Addiction Medicine