ASAM American Society of Addiction Medicine

September 10, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1751-P; Medicare Program; CY 2022 Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (July 23, 2021)

Dear Administrator Brooks-LaSure:

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 Centers for Medicare & Medicaid Services' (CMS) Notice of Proposed Rule Making (Proposed Rule) on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year (CY) 2022, published in the July 23, 2021, Federal Register (Vol. 86, No. 139 FR, pages 39104-39907).

Drug overdose deaths have reached historic highs in this country. Estimates of drug overdose deaths now exceed 94,000 for the 12-month period to January 2021,[i] with overdose death rates surging among Black and Latino Americans.[ii] Alcohol consumption also increased 17 percent between 2019 and 2020.[iii] These spikes in substance use and overdose deaths certainly reflect a combination of increasingly deadly illicit drug supplies, treatment disruptions, social isolation, and other hardships imposed by the COVID-19 pandemic, but they also reflect the longstanding inadequacy of our medical infrastructure when it comes to preventing and treating addiction. Even before the COVID-19 pandemic began, more than 21 million Americans aged 12 or over in 2019 needed

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treatment for a substance use disorder (SUD) in the past year, but only about 4.2 million of them received any treatment or ancillary services for it.[iv]

Given these daunting statistics, ASAM appreciates the opportunity to comment on this proposed rule. Namely, ASAM encourages CMS to:

- Work with Congress to ensure that addiction specialist physicians (ASPs) are not forced to contend with devastating Medicare reimbursement cuts that would further impair patients' critical access to addiction treatment;
- Finalize its proposed OTP coding and payment for a take-home supply of the new, 8 mg naloxone hydrochloride nasal spray product;
- Finalize its proposal to continue to allow opioid treatment programs (OTPs) to furnish therapy and counseling visits using audio-only technologies after the conclusion of the public health emergency (PHE) for COVID–19 and simplify its proposal regarding the documentation of the provision of telehealth services in OTPs;
- Extend its audio-only flexibility proposal for OTPs to the therapy and counseling portions of the bundled payments for SUDs in office-based practices, as well as any additional counseling or therapy that is billed using the add-on code;
- Clarify that SUD services are considered mental health services for purposes of the expanded definition of "interactive telecommunications system" to include audio-only services under 42 C.F.R. § 410.78(a)(3), as well as ensure that in-person requirements shall not apply when audio-only communication technology is used for services for the treatment of a SUD or co-occurring mental health disorder to established patients with a SUD diagnosis so long as an in-person or audio-video telehealth evaluation has occurred;
- Finalize its proposal to implement permanent coverage and payment for HCPCS code G2252 (*Brief communication technology-based service, e.g., virtual check-in service)*; and
- Consider the financial impact of the electronic prescribing requirement on small practices that do not yet have electronic systems in place that allow for electronic prescribing, and accordingly provide additional resources or incentives for these practices to adopt such technology; finalize the proposal to change the EPCS (defined below) compliance date from January 1, 2022 to January 1, 2023, and create an additional exception to the EPCS requirement for clinicians who issue prescriptions for buprenorphine.

Budgetary Adjustments

In the 2022 proposed rule, CMS proposes a CY 2022 PFS conversion factor of $33.58, a decrease of $1.31 from the CY 2021 PFS conversion factor of $34.89. CMS notes that this conversion factor results from the budget neutrality adjustment to account for changes in relative value units (RVUs), and the expiration of the 3.75 percent payment increase provided for CY 2021 by the Consolidated Appropriations Act, 2021 (CAA). Without further Congressional action, this would occur in conjunction with:

- The expiration of the current reprieve from the repeatedly extended 2 percent sequester stemming from the Budget Control Act of 2011;

- Imposition of a 4 percent Statutory PAYGO sequester resulting from passage of the American Rescue Plan Act earlier this year, presumably for at least another 10 years; and
- A statutory freeze in annual Medicare PFS updates under the Medicare Access and CHIP Reauthorization Act (MACRA) that is scheduled to last until 2026, when updates resume at a rate of 0.25% a year indefinitely, a figure well below the rate of medical or consumer price index inflation.

All told, physicians are facing a historic 9.75 percent payment cut beginning on January 1, 2022. More specifically, the subspecialty of addiction medicine is facing a 2.5 percent payment cut from the 2022 physician fee schedule proposal alone. Given the unprecedented nature of the addiction and overdose crisis and the ongoing COVID-19 pandemic, these proposed cuts come at a time when physician practices continue to struggle to recover financially from the unprecedented COVID-19 pandemic. While these cuts would undoubtedly be harmful to the delivery of quality patient care in normal times, they may be catastrophic for some ASP practices and their patients given today's realities. ASPs and other addiction treatment professionals have given their all during the COVID-19 pandemic, ensuring that patients have access to life-saving addiction care in the middle of a global health crisis. **Therefore, it is critical that CMS work with Congress to ensure that ASPs are not forced to contend with devastating Medicare reimbursement cuts that would further impair patients' critical access to quality addiction treatment.**

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Proposed OTP Coding and Payment for New Nasal Naloxone Product

Naloxone is a mu-opioid antagonist with well-established safety and efficacy that can reverse opioid-related respiratory arrest and prevent fatalities. Naloxone is a remarkably effective, inexpensive, and safe medication. It acts quickly and has no addictive potential. The Substance Abuse and Mental Health Services Administration (SAMHSA) supports the use of naloxone for the treatment of opioid overdose by bystanders in their Opioid Overdose Prevention Toolkit. Further, ASAM supports the increased use of naloxone in cases of opioid overdose to prevent or reverse respiratory arrest and supports broadened accessibility to naloxone for people who use drugs and other individuals in a position to initiate early response to evidence of opioid overdose.[v] *In light of the recent approval of a new, higher dose naloxone hydrochloride nasal spray product for opioid overdose,* ***ASAM recommends that CMS finalize its proposed OTP coding and payment for a take-home supply of the new, 8 mg naloxone hydrochloride nasal spray product.***

Counseling and Therapy Furnished via Audio-Only Telephone

In the 2022 proposed fee schedule, CMS proposes to allow OTPs to continue to furnish the therapy and counseling portions of the OTP weekly bundles in Medicare, as well as any additional counseling or therapy that is billed using the add-on code, using audio-only telephone calls rather than via two-way interactive audio-video communication technology after the conclusion of the PHE for COVID–19. CMS would allow this flexibility to be used in cases where audio/video communication is not available to the beneficiary, provided all other applicable requirements are met. CMS is also proposing to require that

when these services are furnished using audio-only technology, practitioners certify that they had the capacity to furnish the services using two-way audio/video communication technology, but used audio-only technology because audio/video communication technology was not available to the beneficiary.

During the PHE, audio-only services have been a vital linkage to care for many patients with SUD, including OUD. 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 communications technology. Audio-only services have helped to advance health equity and have been lifelines to patients leaving incarceration and reentering the community, who often do not have access to two-way, audio-video communication technology. **ASAM strongly supports CMS' proposal to continue this critical audio-only flexibility for OTPs and urges CMS to finalize the proposal.**

CMS' proposals for documenting the provision of audio-visual and audio-only services by OTPs, however, are not clear and could be potentially burdensome. CMS proposes to require that modifier -95 be reported when audio-visual technology is used for the service described by the counseling and therapy add-on code, G2080. CMS also proposes that, after the PHE, OTPs furnishing counseling and therapy services via audio-only, whether as part of the bundled service or an add-on, would need to document in the patient's medical record that this was done and rationale for doing so, and report a modifier. **ASAM urges CMS to simplify this documentation plan to ensure audio-only services are available to patients in OTPs.**

At the same time, ASAM notes that while CMS is proposing to extend this audio-only flexibility for OTP bundles, CMS is not proposing the same for the therapy and counseling portions of the bundled payments for SUDs in office-based practices. Currently, the audio-only flexibility is also scheduled to expire at the conclusion of the PHE for COVID-19 for office-based SUD practices. There are thousands of patients who receive counseling and therapy for the treatment of SUD in office-based practices. A patient's choice of medication for addiction treatment (i.e., methadone can only be provided in OTPs) should not be the deciding factor as to whether such a patient can take advantage of audio-only flexibilities. **ASAM strongly encourages CMS to ensure that its final rule facilitates the provision of audio-only care for Medicare patients needing counseling and therapy for SUD, including OUD, in office-based settings. To that end, ASAM urges CMS to extend its audio-only proposal for OTP bundled payments to the therapy and counseling portions of the bundled payments for SUDs in office-based practices, as well as any additional counseling or therapy that is billed using the add-on code.**

Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology* and *Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA)

CMS also proposes to make certain changes to Medicare telehealth services, including the definition of "interactive telecommunications system." In the proposed rule, CMS proposes to modify the definition of interactive telecommunications system to read: "*Interactive telecommunications system means…[f]or services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home, interactive telecommunications may include two-way, real-time audio-only communication technology if the distant site physician or practitioner is technically capable to use an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology."*

In short, this proposed change would allow physicians to bill for telehealth services provided through audio-only means, so long as they were furnished for the purposes of treating a mental health disorder. This is an important provision that will provide increased access to care for many patients who are struggling with mental health disorders and cannot access treatment in-person or via audio/visual telehealth means. However, it is important to note that many of the same services offered for the treatment of a mental health disorder (e.g., counseling, therapy) can similarly be provided for the treatment of SUD. In fact, as noted above, CMS is using its regulatory authority to continue to allow coverage and payment for audio-only counseling and therapy visits when provided in OTPs.

Given the generalized shortage of addiction treatment professionals,[vi] and the existence of areas and populations where there is limited access to broadband due to geographic or socioeconomic challenges, beneficiaries with a SUD diagnosis may have come to rely upon the use of audio-only communication technology to receive SUD or co-occurring mental health services in settings outside of OTPs. A sudden discontinuation of this flexibility at the end of the PHE could have a negative impact on access to that care. **Therefore, ASAM strongly recommends that CMS explicitly clarify that SUD services are considered mental health services for purposes of the expanded definition of "interactive telecommunications system" to include audio-only services under 42 C.F.R. § 410.78(a)(3), as well as ensure that in-person requirements shall not apply when audio-only communication technology is used for services for the treatment of a SUD or co-occurring mental health disorder to established patients with a SUD diagnosis so long as an in-person or audio-video telehealth evaluation has occurred.**

In parallel, ASAM will continue to advocate for the passage of S. 340 - the Telehealth Response for E-prescribing Addiction Therapy Services (TREATS) Act, which would make explicit Congressional understanding that, with respect to telehealth services furnished to a patient with a SUD diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder, nothing shall preclude the furnishing of such services through audio-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.

Along those same lines, ASAM appreciates that CMS recognizes that the Congressional requirement for a periodic in-person item or service applies only for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder *other than for the treatment of a diagnosed SUD or co-occurring mental health disorder*. ASAM agrees that a claims-based mechanism could be an appropriate way to distinguish between the mental health telehealth services for which payment was newly authorized by the CAA amendments, and those for which payment was authorized before the CAA amendments**. ASAM urges CMS to make it explicitly clear that any requirement that the physician or practitioner must furnish an item or service in person, without the use of telehealth, within a specified time frame shall not apply to telehealth services furnished for treatment of a diagnosed SUD or co-occurring mental health disorder, regardless of whether audio-video or audio-only technology is used**. CMS should leave the determination of when in-person care is necessary for the treatment of a diagnosed SUD or co-occurring mental health disorder to the discretion of the treating clinician. As overdose deaths continue to increase, it is critical that we use every tool in our toolbox to tackle this deadly epidemic.

Other Non-Face-to-Face Services Involving Communications Technology

In ASAM's comments on the proposed 2021 physician fee schedule, ASAM encouraged 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. In this proposed rule, CMS proposes to establish coverage and 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*) on a permanent basis, beginning with the 2022 payment year. **ASAM supports this proposal and requests that CMS implement this proposal as stated.** This new benefit will provide physicians with additional tools to address the ongoing addiction and overdose crisis.

Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

The 2022 proposed MPFS plans to implement the second phase of requirement for electronic prescribing requirement, as required by the SUPPORT Act. This proposed rule would codify certain exceptions to the requirement, including providing exceptions:

- Where the prescriber and dispensing pharmacy are the same entity;
- For prescribers who issue 100 or fewer controlled substance prescriptions for Part D drugs per calendar year; and
- For prescribers who are in the geographic area of a natural disaster, or who are granted a waiver based on extraordinary circumstances, such as an influx of patients due to a pandemic.

CMS is proposing that prescribers be allowed to request a waiver when circumstances beyond the prescriber's control prevent the prescriber from being able to electronically prescribe controlled substances covered by Part D. CMS is also proposing to enforce compliance by sending compliance letters to prescribers violating the mandate but is seeking comments on additional non-burdensome types of compliance actions. CMS is also proposing to extend the start date for compliance actions to January 1, 2023.

ASAM members often prescribe controlled medications to treat addiction. In general, ASAM supports EPCS as a way to assure quality and reduce errors and fraud in the transmission of prescriptions from the prescribing health care practitioner to the dispensing pharmacist. EPCS eliminates the possibility that a patient loses, or a pharmacist misreads a physical prescription note. EPCS can also facilitate reporting of prescriptions to prescription drug monitoring programs (PDMPs).

While ASAM generally supports EPCS, we continue to note that it may not be financially feasible for small practices to implement the required technology. ASAM appreciates that the SUPPORT Act specifies some circumstances under which the Secretary may waive the EPCS requirement for a limited time, including due to demonstrated economic hardship. **ASAM recommends that CMS continue to consider the financial impact of this requirement on small practices that do not yet have electronic systems in place that allow for EPCS, and accordingly provide additional resources or incentives for these practices to adopt such technology. ASAM also recommends that CMS finalize its proposal to extend the start date for compliance actions to at least January 1, 2023. Additionally, consistent with the**

SUPPORT Act's goal of increasing access to evidence-based treatment for OUD and reducing regulatory burdens for clinicians who provide office-based treatment to patients with OUD, ASAM recommends that CMS create an additional exception to the EPCS requirement for clinicians who issue prescriptions for buprenorphine. Specifically, such an additional exception should increase those clinicians' ability to qualify for the low prescription volume exception by excluding buprenorphine prescriptions toward the low prescription volume exception's limit.

Thank you again for the opportunity to provide comments on this important proposed rule. Please contact Corey Barton, Associate Director, Advocacy and Government Relations at cbarton@asam.org or 301-547-4118 with any questions about ASAM's comments. We look forward to continuing to work with CMS to reduce the toll of the addiction and overdose crisis and expand access to evidence-based addiction treatment services.

Sincerely,

William F. Haning, III, MD, DLFAPA, DFASAM
President, American Society of Addiction Medicine

[i] Ahmad, F.B., Rossen, L.M., & Sutton P. (2021). Provisional drug overdose death counts. National Center for Health Statistics.

[ii] Drake, J., Charles, C., Bourgeois, J.W., Daniel, E.S., & Kwende, M. (January 2020). Exploring the impact of the opioid epidemic in Black and Hispanic communities in the United States. Drug Science, Policy and Law. doi:10.1177/2050324520940428

[iii] oi:10.1177/2050324520940428 3 Pollard, M.S., Tucker, J.S., & Green, H.D. Changes in adult alcohol use and consequences during the COVID-19 pandemic in the US. (2020). JAMA Network Open;3(9): e2022942. doi:10.1001/jamanetworkopen.2020.22942

[iv] Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20-07-01-001, NSDUH Series H-55). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from https://www.samhsa.gov/data/.

[v] ASAM's Public Policy Statement on the Use of Naloxone for the Prevention of Opioid Overdose Deaths. Updated July 21, 2021. Accessed September 9, 2021. https://www.asam.org/docs/default-source/public-policy-statements/use-of-naloxone-for-the-prevention-of-opioid-overdose-deaths-final.pdf?sfvrsn=f7c177c2_6.

[vi] SAMHSA. Behavioral health workforce report. (December 2020). Accessed at https://www.mamh.org/assets/files/behavioral-health-workforce-report.pdf.