October 5, 2020

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program – CY 2021 Payment Policies (CMS-1734-P)

To Whom It May Concern:

Thank you for the opportunity to submit comments on the Centers for Medicare & Medicaid Centers’ (CMS) proposed rule to make changes to the physician fee schedule and other changes to the Medicare program. The Legal Action Center (“LAC”) is a non-profit law and policy organization whose mission is to fight discrimination against people with histories of addiction, HIV and AIDS, or criminal records, and to advocate for sound public policies in those areas. As an organization that works to improve access to life-saving substance use disorder (SUD) care, LAC strongly supports CMS’s proposals to the Medicare program to (1) continue furnishing telehealth services via audio-only communication technologies; (2) expand payments for the management and counseling treatment bundled episodes of care to all SUDs; (3) create a new add-on code for the initiation of medication for opioid use disorder treatment in emergency room settings; (4) expand the opioid treatment program benefit to encompass reimbursement for additional services, which these programs are already providing in many cases, and authorize, on a permanent basis, telehealth services for a full range of counseling services; and (5) ensure that beneficiaries receive appropriate assessments for potential SUDs during their initial preventative physical examination and annual wellness visits.

As CMS notes in its proposed rule, about 47,000 Americans died as a result of an opioid overdose in 2018, with 32 percent of these deaths involving a prescription opioid. While overdose death rates declined for the U.S. population as a whole in 2018 and 2019, the rate of overdose deaths among older adults has continued to rise. As of 2019, over 1.2 million individuals ages 65 years and older had a SUD diagnosis, a significant 23% increase from the 974,000 individuals in this age group the previous year. With the increasing rate of SUDs and overdose deaths among older adults, it is vital that CMS

continue to expand access to SUD care, as proposed, and, in the future, take more comprehensive action to cover additional SUD services, provider-types and settings of care so that SUD care is provided on par with other medical conditions.

1. Continuation of Audio-Only Service Delivery Model

LAC strongly supports the continuation of payment for audio-only evaluation and management (E/M) services (CPT codes 99441, 99442, and 99443). As CMS notes in its proposed rule, many Medicare beneficiaries are relying exclusively on audio-only communication technologies for their telehealth services during the COVID-19 Public Health Emergency (PHE) because they lack access to audio-visual communication technologies, and services provided via audio-only communication technologies are serving as a substitute for office/outpatient Medicare telehealth visits. The extended phone services are very helpful for patients who have begun treatment with medications for opioid use disorder (OUD) treatment or psychiatric conditions and require consultation with their practitioner about their treatment progress. We strongly agree that CMS should develop coding and payment for services similar to the virtual check-in but for longer units of time and with accordingly higher values.

In response to CMS’s request for comment on the continued application of these codes, we recommend that these changes be adopted on a permanent basis. There will continue to be Medicare beneficiaries who lack access to audio-visual technology or the technological infrastructure to use such devices; no beneficiary should be deprived of care because of their geographical location, financial status, or level of technological literacy. While audio-only E/M services are important for all beneficiaries, they are of fundamental concern for Medicare patients with SUDs who are allowed by law to receive telehealth services in their homes, not just during the PHE, and may not have the assistance or technology of their providers to access telehealth care via audio-visual platforms.

2. Expanding Payments Under the PFS for Office-Based Management and Counseling Treatment for all Substance Use Disorders

LAC strongly supports the proposal to expand the office-based management and counseling treatment bundled episodes of care payments to include all SUDs, and not just OUD (HCPCS codes G2086, G2087, G2088). According to the 2019 National Survey on Drug Use and Health conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), over one million of the 1.2 million adults ages 65 and over who had a SUD diagnosis in 2019 were dependent on alcohol. Under the current rules, only Medicare beneficiaries with OUD, a small fraction of those with SUDs, are eligible to receive these vital services in office settings, at which they have a trusting relationship with their providers. It is imperative that CMS expand this bundled episode of care to all beneficiaries with SUDs to fill the life-threatening gap in access to coordinated care.

3. Initiation of Medication Assisted Treatment (MAT) in the Emergency Department

We commend and strongly support CMS’s proposal to create a new add-on G-code for initiation of medication for opioid use disorder (MOUD) in the emergency department setting and referral for follow-up care. As the rate of opioid overdose continues to increase during the COVID-19 pandemic, hospital EDs play a more critical role than ever in preventing overdose deaths. EDs are frequently the primary

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3 42 U.S.C. §§ 1395m(m)(4)(C)(ii)(X), 1395m(m)(7).
access point of care for many individuals with a SUD, as they seek emergency care in connection with opioid and other drug overdose and other substance use-related conditions. SUD treatment experts and emergency professionals strongly support the use of MOUD to address withdrawal symptoms and initiate treatment. As noted by CMS, research by D’Onofrio, Busch and others demonstrates that MOUD initiation in EDs is effective in engaging patients in treatment and cost-effective.

Patients served by hospitals around the country will benefit from the proposed add-on G-code, which would pay for assessment, referral to on-going care, follow-up after treatment begins and arranging access to supportive services. Consistent with CMS’s proposal, experts affirm that: (1) interventions in the ED provide “an opportunity to engage patients in a discussion of [opioid agonist therapy] and harm reduction strategies to mitigate risk from the continued use of illicit drugs after discharge” and (2), “following initiation of buprenorphine in the ED, … a warm ‘handoff’ to a treatment provider will improve engagement into long-term treatment.” Notwithstanding these evidence-based practices, hospital EDs frequently cite the lack of resources to provide these services. The proposed billing code will begin to address this significant barrier to care for all SUD patients and incentivize hospital EDs to adopt evidence-based standards of care in their treatment of patients with OUD and other SUDs.

4. Extending the Definition of OUD Treatment Services and Authorizing Additional Services to be Reimbursed by OTPs

A. Adding Naloxone to Bundled Rate

LAC strongly supports the proposal to extend the definition of OUD treatment services to include opioid antagonist medications, such as naloxone, for emergency treatment of opioid overdose and to allow OTPs to be paid under Medicare through the use of add-on codes for dispensing naloxone to Medicare beneficiaries who are receiving other OUD treatment services from the OTP. Naloxone is a life-saving medication that many OTPs are already providing to their patients to prevent opioid overdose. The price of this medication can vary dramatically depending on geographical region, creating cost barriers to patients. Under the proposed standard, patients would gain easy and affordable access to naloxone. We are not providing comments on the proposed payment/pricing methodology and defer to others who have

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7 Our research has determined that hospital EDs in parts of Alabama, California, Colorado, Connecticut, the District of Columbia, Massachusetts, Maryland, Oregon, New York and Rhode Island currently initiate MOUD treatment.


9 We lack cost and other data needed to assess whether the proposed value code is appropriate for these services and, therefore, defer to the experience of ED’s currently delivering these services.

10 American College of Surgeons, Comm. on Trauma, Alcohol Screening and Brief Intervention (SBI) for Trauma Patients available at https://www.facs.org/~media/files/quality%20programs/trauma/publications/sbirtguide.ashx.
gathered cost data that would inform the proposed methodology.

CMS proposes to place frequency limitations on Medicare payments to OTPs for naloxone, providing reimbursement for one add-on code every 30 days. LAC believes that any such limitation is inconsistent with the intent of the proposed rule to make this life-saving drug more accessible and to prevent overdose deaths. Indeed in 2021, 80% of Part D plans placed no quantity limits on naloxone. Although Medicare is not subject to the Mental Health Parity and Addiction Equity Act, imposing limits on access to emergency medication for SUD if similar limits are not imposed on medications for somatic conditions is both discriminatory and arbitrary. CMS should make all efforts to eliminate policies that would hinder access to overdose reversal medications to prevent unnecessary and costly hospitalizations and death.

B. Inclusion of Overdose Education in OUD Treatment Services

LAC also agrees that the definition of OUD treatment services should be further revised to include overdose education and that CMS should establish an add-on payment for OTPs to provide overdose education to the beneficiary and/or the beneficiary’s family or partner. Overdose education, along with naloxone distribution, is one of the most effective tools for reducing opioid overdose deaths. Naloxone is a life-saving medication, but it must be administered properly and promptly when a patient shows signs of an overdose. CMS’s proposal will encourage and incentivize such education by providing adequate reimbursement to OTPs.

C. Delivery of Periodic Assessments via Telehealth

We agree that periodic assessments performed by OTPs, as defined in § 410.67(b)(7), should continue to be allowed to be furnished via telehealth. LAC, however, does not support the proposal to amend the definition of periodic assessments to be limited to face-to-face encounters after the PHE (inclusive of audio-visual telehealth). As noted above, many Medicare beneficiaries lack access to audio-visual communication technologies and are relying on audio-only communication technologies when they use telehealth from their homes. The limitation of periodic assessments to face-to-face encounters would undermine the ability of patients with SUD to get treatment services via telehealth in their homes, as required under the SUPPORT Act.\footnote{42 U.S.C. §§ 1395m(m)(4)(C)(ii)(X), 1395m(m)(7).} If CMS does limit the definition, we strongly encourage CMS to continue to make add-on payments for audio-only periodic assessments furnished by OTPs after the conclusion of the PHE. Given that the audio-only periodic assessments would be provided in lieu of face-to-face assessments and for the same purpose, they should be reimbursed at the same rate.

5. Comprehensive Screening for Potential SUDs in Initial Preventative Physical Examinations and Annual Wellness Visits

LAC strongly supports CMS’s proposal to add new provisions to the regulations for Initial Preventative Physical Examinations (IPPE) and Annual Wellness Visits (AWV) to include screening for potential SUDs and the description of this requirement. Greater integration of SUD and mental health care into primary care settings is essential to prevent and provide early intervention for patients with risky alcohol and drug use and facilitate treatment for patients with SUDs. Providing clear guidance for physicians and practitioners to assess their patients for alcohol and drug use problems will facilitate this integration and evidence-based care. Therefore, we agree with the proposal to amend the IPPE and AWV requirements to describe screening as a review of the individual’s potential risk factors for SUD and referral for treatment as appropriate, and to define “a review of any current opioid prescriptions” to include a review of the potential risk factors to the individual for OUD, an evaluation of the individual’s severity of pain and current treatment plan, the provision of information on non-opioid treatment options, and a referral to a
specialist.

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Thank you for considering our views and for CMS’s commitment to improving access to SUD treatment for Medicare beneficiaries. Please feel free to contact us if you need additional information.

Sincerely,

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