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ADVANCING EMERGENCY CARE

February 13, 2023

The Honorable Miriam E. Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

RIN 0930-AA39

Re: Medications for the Treatment of Opioid Use Disorder

On behalf of the nearly 40,000 members of the American College of Emergency Physicians (ACEP), we appreciate the opportunity to comment on the "Medication for the Treatment of Opioid Use Disorder" proposed rule issued by the Substance Abuse and Mental Health Services Administration (SAMHSA), within the U.S. Department of Health and Human Services (HHS). This rule, among other proposals, would permanently extend the flexibility that SAMHSA granted to Opioid Treatment Programs during the COVID-19 public health emergency (PHE) to allow for the initiation of buprenorphine or methadone via audio-only or audio-visual telehealth technology if an opioid treatment program (OTP) physician (or primary care physician with respect to buprenorphine), or an authorized health care professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via telehealth.

As emergency physicians, we see every day the devastating effects that the opioid crisis has had on the communities we serve. However, ACEP strongly believes that medication for opioid use disorder (MOUD), including buprenorphine and methadone, is an extremely valuable tool in the emergency department (ED) to help start patients with opioid use disorder (OUD) on the path towards recovery. Initiating MOUD in the ED helps individuals stay in treatment longer, reduces illicit opioid use and infectious disease transmission, and decreases overdose deaths.[1] In addition, the available data demonstrate that patients with OUD who are started on buprenorphine in the ED – and for whom there is a clinic to maintain treatment after treatment in the ED – are twice as likely at 30 days to remain in treatment for OUD than patients who receive a referral alone (78 percent of patients started on MOUD in the ED remain in treatment at 30 days, compared to only 37 percent of those who receive a referral alone).[2]

WASHINGTON, DC OFFICE
901 New York Ave, NW
Suite 515E
Washington DC 20001-4432

202-728-0610
800-320-0610
www.acep.org

[1] Bao YP, Wang RJ, et al. Effects of medication-assisted treatment on mortality among opioids users: a systematic review and meta-analysis. Mol Psychiatry. 2018 Jun 22.

[2] D'Onofrio G, O'Connor PG, Pantalon MV, et al, JAMA. 2015 Apr 28;313(16):1636-44.

Additional studies also demonstrate that the initiation of MOUD in the ED leads to increased participation in treatment.[3] [4]

Furthermore, studies of patients with OUD in California and elsewhere have demonstrated an instantaneous reduction in mortality after buprenorphine-assisted detoxification, justifying its use in the ED even when access to long-term maintenance and follow-up is not available.[5] A study conducted using a retrospective chart review of 158 patients treated at a single ED with buprenorphine for opioid withdrawal also found a greater than 50 percent reduction (17 percent versus 8 percent) in return-rate to the same ED for a drug-related visit within one month, compared to the return-visit rate after usual care.[6] Finally, a recent article from JAMA Psychiatry showed that the use of telehealth for the treatment of OUD among Medicare beneficiaries significantly increased during the COVID-19 pandemic. Beneficiaries who received these services were more likely to stay in treatment and less likely to experience an overdose.[7]

Like buprenorphine, methadone is a life-saving medication that can be initiated in the ED to treat patients with OUD. While buprenorphine is more commonly initiated in the ED, methadone is a life-saving alternative treatment option that may be preferred by patients who have not been successful with buprenorphine in managing their OUD.[8] Methadone is associated with high retention rates when flexibly delivered at low fixed doses and has been shown as equally suppressive of illicit opioid use.[9] In all, research suggests that the sooner we can start patients on the right path, and keep them engaged in treatment, the more successful their recovery can be.

Given the proven success of MOUD for the treatment of OUD, ACEP supports the additional flexibility of being able to conduct the initiation via telehealth. However, we note that this proposed rule only governs OTPs, and most of the services provided by emergency physicians fall outside of OTPs, in EDs. We understand that the Drug Enforcement Administration (DEA) has authority over the prescribing of buprenorphine by non-OTP providers. At the beginning of the COVID-19 PHE, the DEA issued waivers to allow DEA-registered practitioners to prescribe controlled substances to their patients without having to interact in-person with their patients. Under the DEA's policy (which became effective on March 31, 2020), authorized practitioners can prescribe buprenorphine over the telephone to new or existing patients with OUD without having to first conduct an examination of the patient in person or via telehealth.

The DEA also plans to issue two regulations regarding the use of telehealth to prescribe controlled substances. One rule relates to the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. The Act required an in-person medical evaluation as a prerequisite to prescribing or dispensing controlled substances, except in the case of

[3] Kaucher K, Caruso E, Sungar G, et al. Evaluation of an emergency department buprenorphine induction and medication-assisted treatment referral program. Am J Emerg Med. 2019 Jul 30.

[4] Hu T, Snider-Adler M, Nijmeh L, Pyle A. Buprenorphine/naloxone induction in a Canadian emergency department with rapid access to community-based addictions providers. CJEM. 2019 Jul;21(4):492-498.

[5] Elizabeth Evans et al., "Mortality Among Individuals Accessing Pharmacological Treatment for Opioid Dependence in California, 2006-10," Addiction 110, no. 6 (June 2015): 996-1005.

[6] Berg ML, Idrees U, Ding R, Nesbit SA, Liang HK, McCarthy ML. Evaluation of the use of buprenorphine for opioid withdrawal in an Emergency Department. Drug Alcohol Depend. 2007;86:239-244.

[7] Jones CM, Shoff C, Hodges K, et al. Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. *JAMA Psychiatry.* Published online August 31, 2022. doi:10.1001/jamapsychiatry.2022.2284.

[8] ASAM. The American Society of Addiction Medicine National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 focused update. *J Addict Med.* 2020;14(2S):1–91.

[9] Mattick RP, Breen C, Kimber J, et al. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane database of systematic reviews.* 2014;(2):CD002207.

practitioners engaged in the practice of telemedicine. The definition of the "practice of telemedicine" includes seven distinct categories that involve circumstances in which the clinician might be unable to satisfy the Act's in-person medical evaluation requirement yet nonetheless has sufficient medical information to prescribe a controlled substance. One specific category within the Act's definition of the "practice of telemedicine" includes a practitioner who has obtained a special registration from the DEA. However, the DEA must issue regulations to effectuate this special registration provisions. This proposed rule would permit such a special registration. The other rule would clarify the ability of clinicians to prescribe buprenorphine to patients with OUD via an audio-only encounter (i.e., by telephone).

Both rules are being reviewed by the Office of Management and Budget within the White House, but it is unclear when they will be issued. ACEP strongly encourages SAMHSA to work with the DEA to get these rules released and implemented as quickly as possible.

With that context in mind, our comments on the rule are as follows.

Take Home Methadone

During the COVID-19 PHE, SAMHSA issued exemptions that allowed state regulatory authorities to request blanket exceptions to allow patients to take home more doses of methadone. With this flexibility, SAMHSA allowed OTPs to dispense 28 days of "take home" methadone doses to "stable" patients for the treatment of OUD, and up to 14 doses of "take home" methadone for "less stable" patients "who the OTP believes can safely handle this level of take home medication. Due to the strong success and support of this temporary flexibility, SAMHSA is now proposing to make it permanent. ACEP supports this proposal and believes that it will make it easier for patients to have access to the medication they need.

The Opioid Treatment Program Flexibility to Prescribe MOUD Via Telehealth Without an Initial In-Person Physical Evaluation

As stated above, ***ACEP strongly supports*** the proposals to makes permanent criteria of initiation of buprenorphine and methadone via audio-only or audio-visual telehealth technology if an OTP physician (or primary care physicians with respect to buprenorphine), or an authorized health care professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via telehealth. We applaud SAMHSA's ongoing effort to reduce regulatory access barriers to this treatment, but again, urge SAMHSA to work with the DEA to permanently extend this flexibility for non-OTP providers as well.

Expanding Access to Services

ACEP supports SAMHSA's proposals to expand harm reduction services to OTP patients, such as counseling on preventing exposure to, and the transmission of, HIV, viral hepatitis, and STIs; providing access to services and treatments for those with HIV, viral hepatitis or an STI; provision of patient-centered harm reduction education; and distribution of opioid overdose reversal medications (e.g., naloxone). With respect to naloxone distribution, ACEP strongly believes that physicians should consider prescribing or distributing naloxone to all individuals at risk of overdose or an individual who may be in a position to save a life from overdose. However, one ongoing barrier to naloxone distribution is a sustainable funding mechanism. ACEP encourages SAMHSA to work with the DEA and other federal and state partners to expand funding for and dispensing of naloxone in EDs and ensure hospitalized patients at risk for overdose leave the hospital with a naloxone kit (not just a prescription) in hand.

To expand access, the proposed rule also expands the definition of "practitioner" to include a "physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife." In addition, the proposed rule expands decision making capacity of OTP practitioners to admission of patients; the provision of treatment activities; and service provision. ACEP strongly believes that all care provided to patients in and out of OTPs should be supervised by physicians. Therefore, we request that SAMHSA explicitly align this new definition of practitioner with a requirement that care be supervised by a physician if provided by a non-physician practitioner.

Other Regulatory Proposed Changes

Terminology Changes

SAMHSA is proposing to now refer to pharmacological treatment for opioid use disorder as "medication for opioid use disorder" (MOUD), which precisely describes the medications being provided, carries less stigma, and aligns with treatment approaches to all other health conditions, instead of the previously used "medication assisted treatment" (MAT). The proposed rule identifies other treatment modalities, such as counseling, by their individual component names, similar to the manner by which elements of other chronic disease care are described. ACEP supports agrees with this name change and believes that it is the most appropriate term to use to describe this important treatment.

ACEP also supports the proposal to remove the term "detoxification treatment" and replace it with "withdrawal management" to reduce stigma.

Opioid Treatment Program Certification

The proposed rule establishes the category of "conditional certification" to allow an OTP to be granted a temporary one-year accreditation to continue treatment services while the OTP takes steps to address issues identified during the accreditation process. The conditions for approval of interim treatment have been amended to increase the duration of interim treatment from 120 days to 180 days, with the stipulation that individuals shall not be discharged without the approval of an OTP practitioner while awaiting transfer to a comprehensive treatment program. The services that can be provided in medication units have been clarified to explicitly allow the full range of OTP services, based on space and privacy available in the medication unit.

ACEP supports the establishment of the category of "condition certification" and the amendments to the conditions for approval of interim treatment and appreciates the clarification of services that can be provided in medication units.

Federal Opioid Use Disorder Treatment Standards

SAMHSA proposes numerous changes to the OUD treatment standards, some of which have not been revised in twenty years.

- ***One-Year Requirement***: One major proposed change is the removal of the requirement that patients must have had an addiction to opioids for at least one year prior to admission for MOUD. The proposed rule instead specifies that the individual should either: meet diagnostic criteria for active moderate to severe OUD; that the individual may be in OUD remission; or that the individual is at high risk for recurrence or overdose. To enhance telehealth flexibility, the requirement to obtain written patient consent to treatment is removed. Consent may be provided verbally or electronically and documented as such. The requirement that individuals under age 18 have two documented unsuccessful attempts at short term withdrawal management ("detoxification") or drug free treatment is also amended to allow consent of a parent, legal guardian, or responsible adult. Further to this, the rule requiring a 1-year history of OUD for people recently released from

penal institutions, pregnant patients or previously enrolled individuals has been removed. Due to the plethora of evidence that MOUD treatment is extremely effective in all cases of patients with OUD, ACEP is supportive of all these proposals.

- *Screening Exams*: The proposed rule allows practitioners who work outside of OTP (with limitations and specific instructions) to undertake an initial screening exam of a patient for OUD. This is likely to reduce delays in diagnosing OUD, initiating MOUD, and in beginning comprehensive treatment. In addition, individuals starting treatment must be screened for imminent risk of harm to self or others. ACEP supports this proposal and believes that it will help expand access to treatment.

- *Treatment at Other OTPs*: SAMHSA proposes to expand the circumstances in which a patient may obtain treatment at another OTP to include instances when there is an inability to access care at the OTP of record. SAMHSA has removed the specific disciplines authorized to administer or dispense MOUD. SAMHSA also proposes to allow OTPs to provide more take home doses of methadone to patients on a more rapid schedule than is permitted in the current regulations as was incorporated in the flexibilities issued during the COVID-19 PHE. ACEP supports these proposals, and again is appreciative of SAMHSA's overall efforts to expand access to MOUD.

- *Take Home Medication:* When determining take home medication schedules under the proposed rule, SAMHSA recommends that the best interest of each patient and the public's health be taken into consideration, and that clinical judgement determine if the therapeutic benefit of take-home medication outweighs the risks to the patient and public health. Therefore, the conditions for interim treatment extend the potential duration of this approach from 120 days to 180 days. Patients must have documented plans for continuation of treatment beyond 180 days and not discharged based on length of time in interim care. ACEP supports this proposal and appreciates the deference to clinical judgment when deciding on take home medication schedules.

- *Mobile Medication Units of OTPs:* Finally, SAMHSA is proposing to waive requirements that mobile medication units of OTPs operating in compliance with the rule separately register at their remote dispensing locations. The range of services that can be provided in medication units are described, which must be delivered in accordance with the nondiscrimination provision that states that "no person shall on the ground of sex (including, in the case of a woman, on the ground that the woman is pregnant), or on the ground of religion, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under section 300x or 300x–21 of this title." ACEP strongly believes that discrimination in any form should be prohibited in health care and therefore we are supportive of this proposal.

Suspension or Revocation of Certification

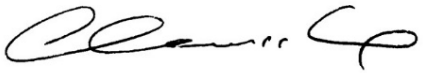
The proposed rule specifies the administrative actions available to SAMHSA in the event that a program sponsor, or any employee of an OTP has: been found guilty of misrepresentation in obtaining certification; failed to comply with the Federal Opioid Use Disorder treatment standards; failed to comply with reasonable requests from SAMHSA or from an accreditation body for records; or refused a reasonable request of a duly designated SAMHSA inspector, DEA Inspector, State Inspector, or accreditation body representative for permission to inspect the program or the program's operations or its records. ACEP supports these proposals.

Authorization to Increase Patient Limit to 275 Patients

The proposed rule removes reporting requirements for those who are authorized to treat up to 275 patients with buprenorphine. ACEP notes that this part of the rule was written before the passage of the *Consolidated Appropriations Act, 2023* (Pub. L,117-328, December 29, 2022) that eliminated the X-waiver requirement and any associated patient limits. This section of the proposed rule is now no longer needed.

We appreciate the opportunity to comment on this proposed rule. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory and External Affairs, at jdavis@acep.org.

Sincerely,



Christopher S. Kang, MD, FACEP
ACEP President