

March 28, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Docket No. DEA-948

Re: Expansion of induction of buprenorphine via telemedicine encounter

Dear Administrator Milgram:

On behalf of the 40,000 members of the American College of Emergency Physicians (ACEP), we wish to comment on the “Expansion of induction of buprenorphine via telemedicine encounter” proposed rule.

Overview

The Drug Enforcement Administration (DEA) is amending its regulations, in concert with the Department of Health and Human Services (HHS), to expand the circumstances in which practitioners are authorized to prescribe buprenorphine via telemedicine for maintenance or detoxification treatment under circumstances to expand access to treatment for opioid use disorder (OUD) while maintaining effective controls against diversion. The DEA believes increasing patient access to medications for opioid use disorder (MOUD) is necessary to both prevent and ameliorate the catastrophic drug poisonings that are occurring as a result of fentanyl.

As emergency physicians, we see every day the devastating effects that the opioid crisis has had on the communities we serve. ACEP strongly believes that MOUD, including buprenorphine, is an extremely valuable tool, both outside and in the emergency department (ED), to help start patients with 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

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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 telemedicine 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

Thus, the body of evidence suggests that access to buprenorphine is an effective – and necessary – step to tackling the current opioid crisis. ***We also believe that emergency physicians can effectively manage patients and prescribe buprenorphine safely via telemedicine without an in-person encounter.*** Several studies have shown that home induction of buprenorphine offers an identical standard of care to in-office induction, with parallel results of successful induction and stabilization given procedural adherence.^{8 9}

With this context in mind, please see the DEA’s specific proposals and ACEP’s comments below.

DEA Proposals

The DEA is proposing to continue to allow the use of telemedicine to initially prescribe buprenorphine for the treatment of MOUD. If allowed by state law, a physician or other practitioner would not only be allowed to prescribe buprenorphine after an audio-video telemedicine encounter but could also prescribe the medication after an audio-only (by phone) visit. However, in these circumstances, the DEA is proposing a prescription limit of 30 days (it can be multiple prescriptions as long as the total number of days does not exceed 30), after which an in-person examination would be required in order to receive refills. The in-person examination can be conducted by the prescriber or by another DEA-registered practitioner. If the in-person examination is done by another practitioner, the prescriber has to participate remotely in a real-time conversation with the practitioner who conducts the in-person examination and the patient. Another way that a physician or practitioner who has never seen the patient in-person

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 Lee JD, Grossman E, DiRocco D, Gourevitch MN. Home buprenorphine/naloxone induction in primary care. *J Gen Intern Med.* 2009 Feb;24(2):226-32. doi: 10.1007/s11606-008-0866-8. Epub 2008 Dec 17. PMID: 19089508; PMCID: PMC2628995.

⁹ Gunderson EW, Wang XQ, Fiellin DA, Bryan B, Levin FR. Unobserved versus observed office buprenorphine/naloxone induction: a pilot randomized clinical trial. *Addict Behav.* 2010 May;35(5):537-40. doi: 10.1016/j.addbeh.2010.01.001. Epub 2010 Jan 18. PMID: 20106601; PMCID: PMC2830372.

can refill a medication past the 30-day initial period via telemedicine is if the virtual prescriber receives a referral from another DEA-registered practitioner. Under this scenario, the patient must have received an in-person medical evaluation from the referring practitioner.

In addition, before prescribing buprenorphine via telemedicine, physicians and other practitioners licensed to prescribe controlled substances must consult a prescription drug monitoring program (PDMP). If the practitioner is unable to consult a PDMP for some reason (if the PDMP is down or if the practitioner is unable to access it), the practitioner can only prescribe up to 7-days' worth of medication until the practitioner is able to consult the PDMP.

The DEA also calls out its concern about diversion and improper use of buprenorphine and that diversion of this medication is dangerous and may lead to misuse and sometimes fatal drug poisonings.

ACEP Comments

Thirty-Day Limit on Prescriptions

ACEP has concerns about the 30-day limitation for buprenorphine prescriptions. We acknowledge the DEA's reasoning that obtaining an in-person medical appointment with a practitioner is often difficult due to the shortage of health care workers and various economic, geographical, sociological, and logistical limitations. However, these limitations are not entirely dissolved after 30 days. Many patients have transportation challenges and inflexible work schedules and must navigate finding an in-network provider that is accepting patients. It also takes significantly longer than 30 days to find an appointment in some areas. **We therefore request that DEA extend the limit to 90 days so patients can more easily maneuver these logistical barriers.**

PDMP Restrictions

ACEP is also concerned with the proposal to limit the buprenorphine prescription to 7 days if a prescriber cannot access a PDMP. ACEP believes that PDMPs play an important role in addressing the opioid crisis as well as deaths related to other prescription drugs. Physicians should make good faith efforts to consult PDMPs before prescribing controlled substances. However, although instances in which a PDMP is inaccessible, such as a server outage, disconnect with the electronic medical record, or a ransomware attack, are rare, they are not impossible occurrences. Infrequent instances in which the PDMP is inaccessible should be documented but should not impede the ability to prescribe a greater supply of buprenorphine, which may cause a disruption in care. Practitioners and patients should not be punished for something out of their control, including non-operational PDMPs. **Therefore, the DEA should omit this requirement from the final rule.**

It is also important to note that some state PDMPs are still in the development stage. Further, although there are states that have seen changes in prescribing behaviors, use of multiple providers by patients, and decreased substance abuse treatment admissions, the data are mixed. A systematic review of the effectiveness of PDMPs by Rhodes et al. concluded that there is limited evidence to support overall associations between PDMPs and reductions in opioid-related consequences.¹⁰ It is unclear why opioid prescribing rates have been shown to decrease in some states after implementation of PDMPs, but no significant changes have been found in others. Studies on the effects of PDMPs on opioid overdoses have similarly been mixed with some studies finding no change in overdose following PDMP

¹⁰ Rhodes, E., Wilson, M., Robinson, A. *et al.* The effectiveness of prescription drug monitoring programs at reducing opioid-related harms and consequences: a systematic review. *BMC Health Serv Res* 19, 784 (2019). <https://doi.org/10.1186/s12913-019-4642-8>

implementation and others finding an increase in overdose.¹¹ Part of the challenge is that there is a wide variation in how PDMPs are implemented in each state, including how they are integrated into EHRs and the time frame for updating new prescriptions. Although all states host PDMPs, some states have not made commitments to make their PDMPs state-of-the-art, and as a result, they are cumbersome, may not contain real-time data, and contain potentially unreliable information. Therefore, given the unreliability of the data in some PDMPs, ACEP feels that it is an acceptable and reasonable policy to allow practitioners to prescribe the maximum length of buprenorphine to patients via telemedicine in the rare circumstances where practitioners are unable to access the PDMP.

Diversions

As alluded to earlier, the DEA includes a discussion of buprenorphine diversion in the proposed rule. We agree with the DEA that “increasing patient access to medication for opioid use disorder is necessary to both prevent and ameliorate the catastrophic drug poisonings that are occurring as a result of fentanyl.” However, the DEA’s assertion that “diversion of buprenorphine and other prescription opioids remains an issue across the country,” necessitating burdensome safeguards around telemedicine opioid prescription requirements, ***is contrary to other studies analyzing buprenorphine misuse***. The DEA’s evidence to make its assertions around diversion are based on findings prior to the COVID-19 public health emergency (PHE), in which flexibilities in prescriptions via telemedicine were granted. Therefore, we believe more investigation is necessary to analyze the effects of telemedicine prescribing of buprenorphine on diversion and health outcomes.

There are also numerous other studies that demonstrate that diversion is decreasing. A study published in 2021 analyzing buprenorphine misuse suggests that prevalence of misuse actually trended downward between 2015 and 2019 (the most recent data available for the study).¹² Furthermore, other studies suggest that programs in which buprenorphine is provided in a non-traditional health care setting absent an in-person medical screening exam, similar to the conditions of telemedicine prescribing, typically result in superior outcomes as compared to patients who were not provided interim medication.¹³

Further, when diversion does occur, it appears from studies that individuals actually wind up using it for its intended purpose, and the only reason why it was diverted initially was because it was difficult to access through the proper channels. In a 2016 study of patients entering treatment for OUD, 81 percent of respondents with any history of diverted buprenorphine usage indicated that easier access to a doctor would encourage them to seek a prescription rather than seeking non-prescription buprenorphine.¹⁴ Respondents reported that physicians prescribing buprenorphine were “hard to find” and they that were often put on long waiting lists while experiencing withdrawal symptoms, which then caused them to seek buprenorphine independently to manage withdrawal.¹⁵ A 2016 study of adults who reported recent non-medical opioid use suggests that motivations for seeking diverted buprenorphine are more commonly to manage withdrawal symptoms (40 percent) and to self-treat OUD (39 percent) than to “get high”

¹¹ Dickson-Gomez J, Christenson E, Weeks M, et al. Effects of Implementation and Enforcement Differences in Prescription Drug Monitoring Programs in 3 States: Connecticut, Kentucky, and Wisconsin. Substance Abuse: Research and Treatment. January 2021. doi:10.1177/1178221821992349.

¹² Han B, Jones CM, Einstein EB, Compton WM. Trends in and characteristics of buprenorphine misuse among adults in the US. JAMA Network Open. 2021;4(10). doi:10.1001/jamanetworkopen.2021.29409

¹³ Williams AR, Mauro CM, Feng T, et al. Non-prescribed buprenorphine preceding treatment intake and clinical outcomes for opioid use disorder. Journal of Substance Abuse Treatment. 2022;139:108770. doi:10.1016/j.jsat.2022.108770

¹⁴ Cicero TJ, Ellis MS, Chilcoat HD. Understanding the use of diverted buprenorphine. Drug and Alcohol Dependence. 2018;193:117-123. doi:10.1016/j.drugalcdep.2018.09.007

¹⁵ Ibid.

(12 percent).¹⁶ Expense is another commonly cited barrier to legal obtainment of buprenorphine; a conjoint analysis of physicians making the decision to start buprenorphine therapy in a new patient suggested that physicians have a clear preference for cash-paying patients and a reluctance to start buprenorphine treatment in patients paying with Medicaid.¹⁷ Thus, patients who do not have the means to pay for medical screening seek buprenorphine elsewhere.

It is also important to note that diversion will also likely decrease (to the extent that exists) as more practitioners begin to prescribe buprenorphine and more people can get access to treatment. The *Consolidated Appropriations Act, 2023* repealed the “X-waiver” requirement for prescribing MOUD at the end of last year. ACEP advocated long and hard for the repeal of this barrier to treatment, which we believed contributed to the stigma around OUD. The removal of the X-waiver now expands the universe of possible prescribers of MOUD from 130,000 to well over a million, which, again, will hopefully enable many more individuals to receive the treatment they need through appropriate channels.

Combining the Buprenorphine Telemedicine Proposed Rule with the Controlled Substances Telemedicine Proposed Rule

The DEA invites comments on whether the Notice of Proposed Rulemaking, entitled “Telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation” (RIN 1117-AB40, referred to as the “Controlled Substances Telemedicine proposed rule”), should be combined with this rulemaking when publishing the Final Rule as both documents refer to prescribing via telemedicine pursuant to 21 U.S.C. 802(54)(G). Since these regulations both address requirements for practitioners engaging in telemedicine, ACEP believes that combining them would alleviate confusion.

It is particularly unclear whether all the policies that apply for prescribing schedule III-V medications and non-narcotics via telemedicine will also apply to buprenorphine and vice versa. For example, the Controlled Substances Telemedicine proposed rule defines a telemedicine relationship established during the COVID-19 PHE, in which patients would be required to undergo an in-person medical evaluation by the prescribing medical practitioner within 30 days of the prescribing date under the rule, as one in which “no later than 180 days have elapsed since [EFFECTIVE DATE OF RULE] or the end of the nationwide public health emergency declared by the Secretary of Health and Human Services on January 31, 2020, as a result of the Coronavirus Disease 2019, whichever is later.” ACEP supports this flexibility, but interestingly, it does not appear to be included in this buprenorphine rule. Further, the Controlled Substances Telemedicine proposed rule permits a prescribing practitioner who receives a qualifying telemedicine referral for the patient to rely on the referring practitioner’s in-person medical evaluation in order to prescribe the controlled substance via telemedicine. However, this referral policy is not referenced in the buprenorphine proposed rule. Combining regulations would bolster consistency across rules and eliminate confusion regarding which policies apply to schedule III-V medications and non-narcotics and which apply to buprenorphine.

We appreciate the opportunity to offer our comments. If you have any questions, please contact Jeffrey Davis, ACEP’s Director of Regulatory and External Affairs, at jdavis@acep.org.

¹⁶ Carroll JJ, Rich JD, Green TC. The More Things Change: Buprenorphine/naloxone Diversion Continues While Treatment Remains Inaccessible. *J Addict Med*. 2018 Nov/Dec;12(6):459-465. doi: 10.1097/ADM.0000000000000436. PMID: 30095563; PMCID: PMC6214787.

¹⁷ Knudsen HK, Lofwall MR, Walsh SL, Havens JR, Studts JL. Physicians’ decision-making when implementing buprenorphine with new patients: Conjoint analyses of data from a cohort of current prescribers. *Journal of Addiction Medicine*. 2018;12(1):31-39. doi:10.1097/adm.0000000000000360

Sincerely,

A handwritten signature in black ink, appearing to read "Christopher S. Kang". The signature is fluid and cursive, with a large initial "C" and a distinct "K" at the end.

Christopher S. Kang, MD, FACEP
ACEP President