Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

Improve Access to Care for Opioid Use Disorder: A Call to Eliminate the X-Waiver Requirement Now

Gail D'Onofrio, MD, MS*; Edward R. Melnick, MD, MHS; Kathryn F. Hawk, MD, MHS

*Corresponding Author. E-mail: gail.donofrio@yale.edu.

0196-0644/$-see front matter
Copyright © 2021 by the American College of Emergency Physicians. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).
https://doi.org/10.1016/j.annemergmed.2021.03.023

A **podcast** for this article is available at www.annemergmed.com.

At the dawn of a new presidential administration, we find ourselves at the crossroads of colliding crises. Action to curb the COVID-19 pandemic has been swift. We now call for similar action from the Federal Government in tackling the opioid epidemic by normalizing medication treatment for addiction. The opioid epidemic is escalating, with over 81,000 drug overdose deaths reported in the 12 months prior to May 2020,[1] primarily driven by the rise in fentanyl use and compounded by the devastating effects of the COVID-19 pandemic, including social isolation, restrictions in treatment and harm reduction services, and disruptions in drug supply.[2] Only 1 in 5 individuals suffering from opioid use disorder receives evidenced-based medications (recommended by the National Academy of Medicine based on their proven effectiveness in reducing withdrawal symptoms, cravings, and infectious diseases and enhancing retention in treatment) to treat their addiction.[3] In addition, the opioid crisis has also highlighted racial and ethnic disparities in care, with Black communities experiencing an 818% increase in synthetic opioid death rates from 2014 to 2017[4]; yet, following an opioid overdose, treatment rates for Black and Hispanic people with opioid use disorder are lower than for non-Hispanic White people.[5]

The Drug Addiction Treatment Act (DATA) initially enacted by Congress in 2000 allowed physicians in ambulatory practices to prescribe treatment for opioid use disorder under very strict guidelines, mandating 8 hours of structured education and obtainment of an X-waiver from the Drug Enforcement Agency (DEA). Allowing access to medication treatment outside of traditional opioid treatment centers was transformative. However, at the time, education on the use of buprenorphine was limited, and the United States was not amid such an escalating opioid crisis. Today, the increasing treatment gap, coupled with high mortality rates and a significant increase in buprenorphine and overall addiction training integrated into professional training and available online, highlights the shifting landscape and a critical need to eliminate the unnecessary regulatory barrier. In fact, France, where all registered physicians have been able to prescribe buprenorphine without special licensing since 1995, has demonstrated remarkable sustained decreases in opioid deaths, with a 79% decline over a 4-year period once restrictions were removed. Additionally, they reported a 95% increase in opioid use disorder treatment, with 80% receiving buprenorphine from an estimated 20% of physicians prescribing buprenorphine in general practice.[6]

The emergency department (ED) is ideally positioned as a low-barrier access point for opioid use disorder treatment. ED-initiated buprenorphine has been demonstrated to increase retention in treatment at 30 days and reduce illicit drug use.[7] The consequences of inaction are real. One study of 17,568 individuals who had nonfatal ED visits for opioid overdose in Massachusetts found that in the 12 months after ED visits, only 17% of individuals were treated with buprenorphine and 11% with methadone, and the 1-year mortality was 4.7% per 100 person years. Those individuals receiving opioid agonist treatment had their risk of dying reduced by 50%.[8] Despite this evidence, adoption has been limited. Focus groups of emergency physicians have identified the X-waiver requirement mandated by DATA 2000 as a key barrier to prescribing.[9] The 8-hour period of specialized training for physicians (24 hours for advanced practice providers), followed by additional onerous regulatory requirements, often delays and discourages prescribing of buprenorphine. These additional requirements include: (1) the practitioner obtaining a certificate from the Substance Abuse and Mental Health Services Administration, (2) the practitioner applying to the DEA, (3) the practitioner waiting weeks to months to receive official notification, and (4) tracking of X-license numbers by health care systems and pharmacies. These excessive requirements reinforce the notion that treating addiction is not the routine responsibility of physicians,

thereby increasing the stigma associated with both addiction and its treatment, thus overall complicating and discouraging a lifesaving intervention. There are no parallel requirements for the treatment of any other medical condition—not even prescribing opioids for pain, including the unrestricted use of buprenorphine for pain control when prescribed by DEA-registered physicians.

The DATA 2000 waiver barrier to expanding opioid use disorder treatment has begun to garner attention from legislators. In 2019, a group of legislators introduced the bipartisan bill "Mainstreaming Addiction Treatment" Act to eliminate the DATA 2000 waiver requirement. Though endorsed by the American Medical Association, American Society of Addiction Medicine, and American College of Emergency Physicians (ACEP), the bill did not pass. On January 14, 2021, the Department of Health and Human Services announced that it would release "Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder" to reduce opioid use disorder treatment barriers by exempting physicians from DATA 2000 certification requirements. Unfortunately, this release was withdrawn due to concerns over the agency's authority to offer such guideline changes. On February 8, 2021, a group of 6 bipartisan legislators wrote to President Biden in support of the Mainstreaming Addiction Treatment Act to invite him to work with Congress to eliminate DATA 2000 requirements. House of Representatives (H.R.) 1384 and Senate (S.) 445 were reintroduced on February 25, 2021, to amend the section of the Controlled Substance Act that requires separate DEA registration to prescribe Schedule III medications for the treatment of opioid use disorder.[10,11]

Passing this legislation to decrease these paradoxical overregulation barriers and enhance broad access to evidence-based treatment for opioid use disorder could have immediate and lasting effects on the worsening opioid crisis in the United States. Critics worry about risks of buprenorphine diversion and inappropriate dispensing with increases in prescribing prevalence.[12] However, the evidence does not support this. A narrative review of 17 studies examining rates and motives for use of unprescribed buprenorphine found that most individuals used the medication for therapeutic indications, to manage withdrawal symptoms or achieve abstinence.[13] Over the past decade, there has been an increase in cash-based buprenorphine practices. While these may, in some cases, seem reminiscent of "pill mills," they are often the only available option for buprenorphine in many communities. Nonetheless, nefarious clinicians in these practices will still be subject to investigation by the DEA and state medical boards despite dissolution of the X-waiver. Finally, there are those concerned that the elimination of the DATA 2000 waiver means that providers will not have needed access to education and training.[14] We strongly advocate for continued integration of substance use disorder education in professional training curricula and that professionals continue to access online and in-person training as needed, just as they would for the treatment of any other medical condition.

Importantly, X-waiver training does not ensure mastery of addiction medicine or ongoing quality of clinical care, and elimination of the waiver requirement would not create a void in clinical education related to opioid use disorder. On the contrary, the developed material for the X-waiver training could be more effectively integrated with other addiction topics and presented across a variety of platforms and formats, including traditional didactic, online webinars, interactive cases, and free open access medical education. Topics incorporated into medical and allied health professional training would *normalize* education about the clinical care of addiction. Since 2018, more than 800 EDs have voluntarily registered to complete a structured quality improvement project and participate in an online learning collaborative through the ACEP Emergency Quality Network.[15] ACEP has supported the development and delivery of dozens of webinars, talks, and educational resources on treating addiction and opioid use disorder in the ED. Within 24 hours of the US Department of Health and Human Services' announcement to exempt physicians from DATA 2000 waiver requirements, ACEP started planning the development of concise, ED-focused opioid use disorder treatment education for emergency physicians, similar to other lifesaving interventions such as thrombolytics or percutaneous transluminal coronary angioplasty for acute ST-elevation myocardial infarction.

Emergency physician knowledge and experience initiating buprenorphine can also be improved by making high-quality evidence available at the point of care. When DATA 2000 was enacted, real-time computerized clinical decision support was not as readily available as it is today. Recently, an integrated, user-friendly tool to support clinicians of varying levels of expertise prescribing buprenorphine was developed and tested within multiple electronic health records. This approach streamlines what can be an unfamiliar, complex workflow into a few mouse clicks. Pilot testing of this intervention was associated with a near doubling in the proportion of unique attending physicians adopting the practice of ED initiation of buprenorphine.[16] Effectiveness testing is now underway in a 20-site group randomized trial. Such digital health solutions that walk clinicians through every step of

buprenorphine initiation have the potential to make this practice safer and more effective for novice prescribers than unsupervised practice following waiver training.

The ED offers a 24/7/365 option for accessing buprenorphine treatment, often when individuals are most ready to act, presenting with an overdose, infection, or seeking treatment. This access point provides a critical opportunity to intervene as the risk of death after presenting to an ED with a nonfatal overdose is high.[8] Emergency physicians should be able to initiate a lifesaving treatment for a life-threatening disease and refer patients to any primary care practice to continue treatment as they would for any other disease that has been stabilized for ongoing management. Removing regulatory requirements would be a giant step forward in reducing the disparities in access to evidence-based treatment of opioid use disorder. All physicians who are in a position to prescribe buprenorphine would benefit from these changes. Physicians should encourage the current US administration and Congress to swiftly end the prescribing restrictions generated by DATA 2000.

Addendum: On April 27, 2021 DHHS released new federal practice guidelines for buprenorphine. This work around allows physicians and advanced practice practitioners, who agree to treat no more than 30 patients time, to longer need extra hours of training to prescribe buprenorphine or have to refer patients to counseling services. However, providers must still send a notice of intent to SAMHSA to receive a restricted X waiver. While eliminating the training component, this process is onerous taking ∼45 days to complete. Congress still needs to pass the MAT Act to improve access to OUD treatment.

Supervising editor: Donald M. Yealy, MD. Specific detailed information about possible conflict of interest for individual editors is available at https://www.annemergmed.com/editors.

Author affiliations: From the Department of Emergency Medicine, Yale School of Medicine, New Haven, CT (D'Onofrio, Melnick, Hawk).

Funding and support: By *Annals* policy, all authors are required to disclose any and all commercial, financial, and other relationships in any way related to the subject of this article as per ICMJE conflict of interest guidelines (see www.icmje.org). The authors have stated that no such relationships exist.

REFERENCES

1. Increase in Fatal Drug Overdoses Across the United States Driven by Synthetic Opioids Before and During the COVID-19 Pandemic. Centers for Disease Control and Prevention. Accessed January 8, 2021. https://emergency.cdc.gov/han/2020/han00438.asp
2. D'Onofrio G, Venkatesh AK, Hawk. The adverse impact of COVID-19 on individuals with OUD highlights the urgent need for reform to leverage ED-based treatment. *NEJM Catal Innov Care Deliv*. 2020. https://doi.org/10.1056/CAT.20.0190
3. National Academies of Sciences, Engineering, and Medicine. *Medications for Opioid Use Disorder Saves Lives*. The National Academies Press; 2019. https://doi.org/10.17226/25310.
4. James K, Jordan A. The opioid crisis in Black communities. *J Law Med Ethics*. 2018;46:404-421. https://doi.org/10.1177/1073110518782949.
5. Kilaru AS, Xiong A, Lowenstein M, et al. Incidence of treatment for opioid use disorder following nonfatal overdose in commercially insured patients. *JAMA Netw Open*. 2020;3:e205852. https://doi.org/10.1001/jamanetworkopen.2020.5852
6. Auriacombe M, Fatseas M, Dubernet J, et al. French field experience with buprenorphine. *Am J Addict*. 2004;13:S17-S28.
7. D'Onofrio G, O'Connor PG, Pantalon MV, et al. Emergency department-initiated buprenorphine/naloxone treatment for opioid dependence: a randomized clinical trial. *JAMA*. 2015;313:1636-1644. https://doi.org/10.1001/jama.2015.3474
8. Larochelle MR, Bernson D, Land T, et al. Medication for opioid use disorder after nonfatal opioid overdose and association with mortality: a cohort study. *Ann Intern Med*. 2018;169:137-145. https://doi.org/10.7326/M17-3107
9. Hawk KF, D'Onofrio G, Chawarski MC, et al. Barriers and facilitators to clinician readiness to provide emergency department-initiated buprenorphine. *JAMA Netw Open*. 2020;3:e204561. https://doi.org/10.1001/jamanetworkopen.2020.4561
10. 117th Congress. H.R. 1384 - To amend section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) to eliminate the separate registration requirement for dispensing narcotic drugs in schedule III, IV, or V (such as buprenorphine) for maintenance or detoxification treatment, and for other purposes. 2021. Accessed March 12, 2021. https://www.congress.gov/bill/117th-congress/house-bill/1384?q=%7B%22search%22%3A%5B%22H.R.+1384%22%5D%7D&s=2&r=1
11. 117th Congress. S.445 - Mainstreaming Addiction Treatment Act of 2021. 2021. Accessed March 12, 2021. https://www.congress.gov/bill/117th-congress/senate-bill/445?q=%7B%22search%22%3A%5B%22S.+445.%22%5D%7D&s=1&r=1
12. Lofwall MR, Walsh SL. A review of buprenorphine diversion and misuse: the current evidence base and experiences from around the world. *J Addict Med*. 2014;8:315-326.
13. Chilcoat HD, Amick HR, Sherwood MR, et al. Buprenorphine in the United States: motives for abuse, misuse, and diversion. *J Subst Abuse Treat*. 2019;104:148-157.
14. Weimer MB, Wakeman SE, Saitz R. Removing one barrier to opioid use disorder treatment: is it enough? *JAMA*. 2021;325:1147-1148. https://doi.org/10.1001/jama.2021.0958
15. E-QUAL Network Opioid Initiative. American College of Emergency Physicians. Accessed March 11, 2021. https://www.acep.org/administration/quality/equal/emergency-quality-network-e-qual/e-qual-opioid-initiative/
16. Holland WC, Nath B, Li F, et al. Interrupted time series of user-centered clinical decision support implementation for emergency department-initiated buprenorphine for opioid use disorder. *Acad Emerg Med*. 2020;27:753-763.