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EDITORIAL



No end to the crisis without an end to the waiver

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In the midst of the worst drug overdose crisis in US history, the majority of health care providers are prohibited from providing the full range of evidence-based treatment for opioid use disorder (OUD). As of December 2017, nearly 48,000 Americans died of an opioid overdose in the prior year; overdose deaths involving highly potent synthetic opioids tripled in the past 2 years to more than 28,000.¹ Medications for OUD, such as buprenorphine and methadone, decrease all-cause and overdose mortality, but these evidence-based treatments remain vastly underutilized.² Buprenorphine treatment, in particular, holds promise for the increasing numbers of patients with an OUD, particularly as the dispensation of methadone for the treatment of OUD is limited to those programs—not practitioners—that are licensed to provide this treatment, programs often difficult to create, staff, and maintain.^{3–5} Until we identify and remove all barriers to OUD treatment in all health care settings, the opioid overdose crisis will continue. One barrier in particular stands in the way of meaningful expansion of OUD treatment: the buprenorphine waiver system. Real reform to this system is urgently needed.

Limitations on medication treatment of OUD can be traced as far back as the Harrison Narcotics Tax Act of 1914, which created a system of registration and taxation of the production and distribution of opium and cocaine products.⁶ This law specifically exempted provision of these products if delivered by a health care provider “in the course of his professional practice only.” This law was the focus of a series of Supreme Court decisions in subsequent years. Most notably, in *Jin Fuey Moy v. United States* in 1920, the Court’s decision barred the provision of medications “intended to cater to the appetite or satisfy the craving of one addicted to the use of the drug.”⁷ This nearly century-old decision laid the foundation for our current policy environment in which methadone and buprenorphine are substantially restricted for the treatment of OUD but can be prescribed for pain with relatively little oversight. More than 50 years later, the Narcotic Addict Treatment Act of 1974 created special registration requirements to allow for the treatment of OUD with “narcotic drugs” such as buprenorphine and methadone.⁸ More recently, the Drug Addiction

Treatment Act of 2000 (DATA2000), signed into law in 2002, created a process by which qualified prescribers could apply for “waivers” of these registration requirements in order to prescribe qualified medications—US Food and Drug Administration (FDA) Schedule 3, 4, 5 medications approved for OUD treatment—in any health care setting.⁹ To date, buprenorphine and buprenorphine/naloxone are the only medications approved under DATA2000 be prescribed in this manner.

To qualify to prescribe, physicians must meet one of several requirements; most providers qualify for the ability to prescribe by completing no less than 8 hours of training through a DATA2000 accredited training organization in the diagnosis and management of OUD. After training, the practitioner must request a waiver from the Drug Enforcement Agency (DEA). Prescribers are initially limited to 30 patients; after 1 year of prescribing, prescribers can apply to increase this limit to 100, and after an additional year prescribers who meet specific criteria can increase this limit up to 275 patients. After receipt of the waiver, as long as the prescriber has a valid DEA license and the ability to practice medicine, no additional educational or recertification requirements are necessary. More recently, the Comprehensive Addiction and Recovery Act (CARA) of 2016 expanded buprenorphine prescribing authority to nurse practitioners (NPs) and physician assistants (PAs), who must complete 24 hours of training to qualify.^{10,11}

The buprenorphine waiver system was intended to expand access, but the availability of office-based treatment of buprenorphine remains woefully inadequate. Less than 5% of practicing physicians, NPs, and PAs are waived to prescribe buprenorphine.¹² Four out of 5 people with an OUD diagnosis do not receive evidence-based treatment or treatment within health care settings.¹³ As overdose deaths continue to climb, the harms of inadequate access to evidence-based OUD treatment are now very different than they were 18 years ago. In 2018, health care providers and public health practitioners must advocate for the widespread implementation of all available evidence-based strategies and for the de-implementation of policies for which the benefits no longer outweigh the harms.

The buprenorphine waiver system serves as a barrier in several ways. The required 8 hours of training for physicians and 24 hours for NPs and PAs prohibit many busy health care providers from offering this treatment. Many clinicians who undergo the 8 hours of training do not apply for the waiver. In addition, many clinicians who do receive the waiver do not prescribe and those who do prescribe often prescribe less than their limits would allow.^{14–17} Perhaps in the process of obtaining the waiver, aspects of the training or process discourage some providers from prescribing the medication. Perhaps from the time the practitioner expresses interest in the prescribing OUD pharmacotherapy to receipt of the waiver, the interest fades. Perhaps the patient who prompted the clinician's interest to prescribe is long gone from the office or emergency room setting. Perhaps other barriers to prescribe (e.g., credentialing and privileging processes, prior authorization procedures, requirements for non-pharmacologic treatment) reduce interest or impede the ability to prescribe.^{5,18} Perhaps more importantly, as long as additional training is required, the treatment itself will remain stigmatized and separate from mainstream health care practice. The training requirement may heighten fears that buprenorphine treatment is more challenging or dangerous than other chronic disease management that health care providers routinely provide. In fact, buprenorphine is less risky than many medications physicians commonly prescribe, including full opioid agonists. These perceptions impact treatment availability not only for primary care and mental health providers but also in the many other settings in which patients with OUD receive care: the emergency department and the hospital obstetrics and infectious disease departments.¹⁹

Buprenorphine waiver training offers benefits, but those benefits are unlikely to outweigh the harms of inadequate access to OUD treatment. Potential benefits of waiver training include higher quality of care and decreased risk of misuse or diversion. However, it has not been shown that buprenorphine waiver training improves provider knowledge, patient care, or patient outcomes. Additionally, to obtain a waiver, providers must affirm their capacity to refer patients for counseling and other services. Expanded access to individualized psychosocial treatment for OUD is important, but the “capacity to refer” does not ensure that these treatments are available, affordable, or appropriately matched to patients' needs. Reform to the buprenorphine waiver system should be accompanied by expanded training in the management of substance use disorders, including but not limited to buprenorphine treatment, at all training levels and within all health care disciplines.

For guidance on the potential benefits and harms of an end to the buprenorphine waiver system, we can look to France. Since 1995, all medical doctors in France have been allowed to prescribe buprenorphine without any special education or licensing. Within 5 years, the number of opioid overdose deaths declined by 79%.²⁰ The number of individuals with OUD receiving treatment increased from less than 2000 to more than 60,000 per year. Critics of expanding buprenorphine access raise legitimate concerns about the

risk of diversion or misuse of buprenorphine, especially if prescribers were to receive less than 8 hours of training. As buprenorphine is a partial opioid agonist, there is a limit to how much euphoria and respiratory depression it can produce. Buprenorphine may still result in overdose if used with sedatives and/or alcohol, but it is less risky than illicit synthetic opioids or full opioid agonists prescribed for pain. Prior studies in the United States suggest that most diverted buprenorphine is used therapeutically to control cravings.²¹ In France, adverse outcomes related to misuse were outnumbered by declines in overdose deaths. As in France, reform of the buprenorphine waiver system in the United States should be accompanied by rigorous evaluation of individual- and community-level outcomes.

There are, of course, important differences between the French health care system and our own. The French system offers near-universal insurance coverage and reimburses OUD treatment as it does that of other chronic conditions. Treatment expansion in France occurred alongside programs to expand syringe services programs and center-based methadone treatment and relied heavily on pharmacists to supervise dispensing and coordinate with prescribers. It is this type of multifaceted, cross-sector investment that is currently needed in the United States. Reform of the buprenorphine waiver system is necessary but insufficient. It must be accompanied by incentives such as improved reimbursement for OUD care and by the removal of other barriers such as burdensome prior authorization requirements. Still, reform of the buprenorphine waiver system would send a powerful message to individuals, families, and communities struggling with opioid addiction. It would accelerate uptake of OUD treatment in mainstream health care practice, reducing stigma and improving access to an evidence-based tool for treatment and recovery.

A number of measures in the bipartisan opioid legislation passed in October 2018 will impact the buprenorphine waiver system. This legislation will create a second pathway for medical trainees to complete at least 8 hours of training and obtain a waiver immediately as they enter practice. It will also make permanent the buprenorphine prescribing authority of NPs and PAs and temporarily expand prescribing to additional nursing specialties. These are positive but incremental steps at a time when expansion of the OUD treatment workforce is urgently needed. To most rapidly increase this workforce, we could end the separate buprenorphine waiver system altogether, unwinding a policy framework that was set in motion more than 100 years ago and treating buprenorphine like other controlled substances such as full agonist opioids. If this would be too drastic for policymakers, simple steps to address administrative burdens would include making the training more readily accessible, available on-demand, online, and free. Policymakers could mandate training during medical school and residency or provide waivers at the level of facilities or health systems rather than to individual providers. Alternatively, a more responsive waiver system might allow prescribers to provide buprenorphine treatment to a limited number of patients (e.g., 6 or 12 patients) without the waiver requirements and,

if the prescriber wishes to prescribe to more patients, then mandate additional training. This would encourage immediate treatment to those who need it as they encounter health care providers.

To meet the challenge of the worst drug overdose crisis in US history, we must identify and address all barriers to evidence-based, life-saving treatment. To expand patients' access to OUD treatment, we must critically reexamine and reform the buprenorphine waiver system without delay.

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Author contributions

J.F, S.W, A.G.: conception and design. J.F, S.W, A.G.: research. J.F, S.W, A.G.: composition.

References

- [1] Ahmad F, Rossen L, Spencer M, Warner M, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2018. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm?wpisrc=nl_health202&wpm=1. Accessed August 9, 2018.
- [2] Sordo L, Barrio G, Bravo MJ. Mortality risk during and after opioid substitution treatment: systematic review and meta-analysis of cohort studies. *BMJ*. 2017;357:j1550
- [3] Oliva EM, Trafton JA, Harris AH, Gordon AJ. Trends in opioid agonist therapy in the Veterans Health Administration: is supply keeping up with demand? *Am J Drug Alcohol Abuse*. 2013;39(2):103–107.
- [4] Wyse JJ, Gordon AJ, Dobscha SK, et al. Medications for opioid use disorder in the Department of Veterans Affairs (VA) Health Care System: historical perspective, lessons learned and next steps. *Subst Abus*. 2018 Mar 29. [Epub ahead of print]. doi: 10.1080/08897077.2018.1452327
- [5] Oliva EM, Maisel NC, Gordon AJ, Harris AH. Barriers to use of pharmacotherapy for addiction disorders and how to overcome them. *Curr Psychiatry Rep*. 2011;13:374–381.
- [6] Courtwright DT. Preventing and treating narcotic addiction—century of federal drug control. *N Engl J Med*. 2015;373:2095–2097.
- [7] *Jin Fuey Moy v. United States*, 254 U.S. 189 (1920). <https://www.law.cornell.edu/supremecourt/text/254/189>. Accessed October 22, 2018.
- [8] Narcotic Addict Treatment Act of 1974. Public Law No. 93–281. <https://www.gpo.gov/fdsys/pkg/STATUTE-88/pdf/STATUTE-88-Pg124.pdf>. Accessed August 9, 2018.
- [9] Drug Addiction Treatment Act of 2000. Public Law No. 106–310, Title XXXV. <https://www.congress.gov/106/plaws/publ310/PLAW-106publ310.pdf>. Accessed August 9, 2018.
- [10] Comprehensive Addiction and Recovery Act of 2016. Public Law No. 114–198. <https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf>. Accessed August 9, 2018.
- [11] Tierney M, Finnell DS, Naegle MA, LaBelle C, Gordon AJ. Advanced practice nurses: Increasing access to opioid treatment by expanding the pool of qualified buprenorphine prescribers. *Subst Abus*. 2015;36:389–392.
- [12] Physician and Program Data. <https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/physician-program-data>. Accessed October 22, 2018.
- [13] Wu LT, Zhu H, Swartz MS. Treatment utilization among persons with opioid use disorder in the United States. *Drug Alcohol Depend*. 2016;169:117–127.
- [14] Valenstein-Mah H, Hagedorn H, Kay CL, Christopher ML, Gordon AJ. Underutilization of the current clinical capacity to provide buprenorphine treatment for opioid use disorders within the Veterans Health Administration. *Subst Abus*. 2018 Oct 16 [Epub ahead of print]. doi: 10.1080/08897077.2018.1509251.
- [15] Stein BD, Sorbero M, Dick AW, et al. Physician capacity to treat opioid use disorder with Buprenorphine-Assisted treatment. *JAMA* 2016;316:1211–1212.
- [16] Jones CM, Campopiano M, Baldwin G, McCance-Katz E. National and state treatment need and capacity for opioid agonist Medication-Assisted treatment. *Am J Public Health*. 2015;105:e55–e63.
- [17] Gordon AJ, Liberto J, Granda S, et al. Outcomes of DATA 2000 certification trainings for the provision of buprenorphine treatment in the Veterans Health Administration. *Am J Addict*. 2008;17:459–462.
- [18] Gordon AJ, Liberto J, Granda S, et al. Physician training is never a failure. *Am J Addict*. 2009;18:337–338.
- [19] Wakeman SE, Barnett ML. Primary care and the Opioid-Overdose Crisis-Buprenorphine myths and realities. *N Engl J Med*. 2018;379:1–4.
- [20] Fatseas M, Dubernet J, Daoulouede J-P, Auriacombe M. Buprenorphine in the Treatment of Opioid Addiction: The French Experience. In: el-Guebaly N, Carra N, Galanter M, eds. *Textbook of Addiction Treatment: International Perspectives*. Vol 1. New York, NY: Springer; 2015.
- [21] Schuman-Olivier Z, Albanese M, Nelson SE, et al. Self-treatment: illicit buprenorphine use by opioid-dependent treatment seekers. *J Subst Abuse Treat*. 2010;39:41–50.