Federal Barriers to Addressing the Opioid Epidemic

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In 2017, there were more than 47,000 opioid-associated overdose deaths in the United States, and the Department of Health and Human Services declared that the opioid epidemic was a public health emergency. Over the past few years, Congress has passed considerable legislation to address opioid use disorders (OUDs), including the Comprehensive Addiction and Recovery Act in 2016, the 21st Century Cures Act in 2016, and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act in 2018. These laws provide funding to study non-narcotic pain management, monitor opioid prescribing, enhance prevention of substance use disorders, and train clinicians in addiction treatment, among other measures.

Although these congressional initiatives are encouraging, federal regulations still limit access to evidence-based treatments for OUDs and the adoption of internationally accepted practices. There are numerous ways to improve the prevention, diagnosis, and treatment of OUDs in the USA, including limiting unnecessary prescriptions of opioids, screening for OUDs in primary care, and streamlining linkages between internists and addiction specialists. However, just a few of these approaches are specifically impeded by existing federal regulations. This article examines several ways in which top-down federal barriers prevent implementation of evidence-based OUD treatments.

METHADONE

Imagine if patients who rely on insulin to treat diabetes had to wake up early in the morning, travel to a highly regulated clinic miles away, then wait in line to access this life-saving medication. This ordeal is a daily reality for patients across the USA who rely on methadone for OUD treatment. Methadone is an opioid agonist that can reduce mortality risk among patients with OUDs by half or more, yet remains stigmatized and subject to strict regulations. Title 42 of the Code of Federal

Regulations (CFR) Part 8, shaped by the Controlled Substances Act of 1970 and the Narcotic Addict Treatment Act of 1974, restricts outpatient methadone prescribing for addiction treatment to opioid treatment programs (OTPs). Federal regulations for OTPs include extensive certification criteria, Drug Enforcement Agency (DEA) audits, and limits to the amount of medication dispensed to each patient.

These regulations diminish access to a life-saving treatment. Approximately 1700 OTPs serve over 380,000 patients in the USA^{1,2}; however, for many Americans in rural or urban areas, accessing an OTP is not feasible given the time, money, and travel required. A 2015 study found 87% of US counties had shortages in the availability of OTPs, a figure which rose above 97% for counties with populations below 20,000.³ Methadone use carries risks, most notably of overdose and respiratory depression, particularly during induction, of QTc prolongation, and of medication diversion from its intended use. However, these burdensome regulations around methadone are specific to the OUD diagnosis, discriminating against and stigmatizing patients with OUDs. When used to treat pain, methadone may be prescribed by physicians with DEA licenses and dispensed by community pharmacies without the same degree of regulatory burdens.

For example, enabling methadone prescribing in outpatient settings beyond OTPs would expand access in places where OTPs are unavailable or inconveniently located. To mitigate the risks of methadone, initiation of the medication could be undertaken by outpatient addiction specialists or primary care physicians (PCPs) whose scope of practice includes OUD treatment. Once taking a stable dose, patients should have the option of continuing maintenance treatment in either specialty addiction clinics or primary care settings. Observed or take-home doses could be dispensed at community pharmacies, thereby maintaining structured access and reducing diversion risks. For patients who would benefit from psychosocial supports currently offered by OTPs, PCPs can refer patients to addiction services in the community, such as individual counseling, group therapy, and peer support networks. By reforming provisions on methadone prescribing in 42 CFR 8, policymakers can leverage existing networks of PCPs, addiction specialists, and more than 80,000 pharmacies across the USA to increase access to methadone while still mitigating risks of diversion, respiratory depression, and overdose.^{4,5} These reforms would place US methadone policies more in line with those of other industrialized nations, including the UK, Australia, and Canada.⁴

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BUPRENORPHINE

Buprenorphine is another evidence-based treatment for OUDs that reduces mortality and illicit substance use. The Drug Addiction Treatment Act of 2000 enables office-based prescriptions of buprenorphine to treat OUDs, but federal regulations impose barriers around this medication. Clinicians cannot prescribe buprenorphine to an outpatient seeking OUD treatment unless they first undergo 8 h of specialty training, apply for an X waiver from the Substance Abuse and Mental Health Services Agency, initially limit prescriptions to 30 patients, and maintain additional record-keeping for possible DEA audits. These requirements place unique burdens on clinicians caring for patients with OUDs, dissuade prescribers from providing buprenorphine treatment, stigmatize OUDs, and separate addiction treatment from other medical care. Internists who work on the frontlines of US health care and who bring expertise in treating chronic medical conditions are well-positioned to offer buprenorphine to patients with OUDs but may find themselves deterred from doing so by these regulatory barriers. A study of US counties found that, at the end of 2017, 42.3% of all counties and 69.3% of counties whose largest town had fewer than 10,000 residents lacked a waived clinician who could prescribe buprenorphine for OUDs.⁶

In 1995, France began allowing clinicians to prescribe buprenorphine without additional licensing, which corresponded with a fall in opioid overdose deaths by nearly 80% over the next few years.⁷ Congress should similarly eliminate the X-waiver requirement for buprenorphine, allowing clinicians with DEA licenses to prescribe buprenorphine for treating OUDs. While the X-waiver may be intended to reduce diversion and to protect patients from unscrupulous prescribing, buprenorphine can already be prescribed for pain in the USA without a waiver and has fewer risks of respiratory depression or fatal overdose than full opioid agonists that are prescribed with less training or oversight.⁷ By removing this waiver requirement, policymakers can increase the availability of clinicians who can offer buprenorphine treatment, reduce disruptions in continuity of care, decrease the stigmatizing effects of these unique regulatory burdens, and potentially mitigate OUD-related morbidity and mortality.

SUPERVISED CONSUMPTION SERVICES AND HEROIN-ASSISTED TREATMENT

Implemented in Australia, Canada, France, Germany, Netherlands, Spain, and Switzerland, among other countries, supervised consumption services (SCSs) are harm reduction sites where patients can use substances under supervision by medical professionals who can offer treatment services and respond to adverse events. Proposals for SCSs have arisen in at least 8 US states, but the US Department of Justice considers these facilities illegal under the Controlled Substances Act and has sued to prevent a proposed facility in Pennsylvania.

Existing evidence suggests SCSs achieve numerous harm reduction goals, including decreases in overdose deaths, enhanced access to treatment services, and promotion of safe injection practices.⁸ Critics have raised reasonable concerns about SCSs, including whether these facilities concentrate substance use into nearby areas and increase publicly discarded syringes. Further, much of the existing research on SCSs consists of non-randomized studies with methodological limitations. With the lack of SCS effectiveness studies in the USA and perceptions that SCSs facilitate substance use, policymakers may be hesitant to consider measures permitting SCSs. Yet, given their potential to enhance patient safety and to reduce unwitnessed overdoses, SCSs should be studied rather than litigated against. By modifying the Controlled Substances Act to allow research into SCSs, Congress could enable medical professionals to evaluate a treatment approach that has been embraced internationally and that could save lives. In particular, these reforms could provide clinicians with new opportunities to engage with marginalized patients who might not otherwise obtain medical or substance use treatment.

Furthermore, many patients continue to experience adverse consequences of OUDs despite treatment with currently available medications and psychosocial interventions. In at least 8 other countries, supervised injection of pharmaceutical-grade heroin (i.e. diacetylmorphine or diacetylmorphine) is an evidence-supported option for patients with treatment-resistant OUDs and who are at high risk of morbidity and mortality, including overdose death. A 2015 meta-analysis of 6 open-label randomized controlled trials found medically prescribed heroin could reduce illicit heroin use and was more effective at treatment retention than oral methadone.⁹ Additional research is needed to determine whether prescribed heroin may be beneficial for OUD treatment in US contexts. Nonetheless, the US federal categorization of heroin as a schedule I drug with “no currently accepted medical use in treatment in the United States” impedes these kinds of research. Re-scheduling heroin alongside other controlled substances with therapeutic value, including cocaine and amphetamines, is one potential path forward. The current US regulatory framework hinders exploration of potentially innovative treatments and harm-reduction strategies for patients with treatment-resistant OUDs.

CONCLUSIONS

Federal regulations maintain top-down frameworks around OUD treatment that hamper the US response to the opioid epidemic. These regulations decrease patient access to potentially life-saving OUD treatments, limit the availability of clinicians who can treat OUDs, stigmatize OUDs, and prevent the study and adoption of treatment models embraced in international settings. Without restructuring the foundations of addiction treatment in the USA to remove these barriers,

lawmakers' efforts to decrease opioid-related morbidity and mortality will remain constrained. By removing these barriers, policymakers can help millions of Americans access evidence-based OUD treatments that are too often kept out of reach.

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Compliance with Ethical Standards:

Conflict of Interest: The authors declare that they do not have a conflict of interest.

REFERENCES

1. **Substance Abuse and Mental Health Services Administration.** National Survey of Substance Abuse treatment Services (N-SSATS):2017. Data Substance Abuse Treatment Facilities. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2018
2. **Substance Abuse and Mental Health Services Administration.** Opioid Treatment Program Directory. Available from: <https://dpt2.samhsa.gov/treatment/directory.aspx>. Accessed 3 Feb 2020.
3. **Dick AW, Pacula RL, Gordon AJ,** et al. Growth In Buprenorphine Waivers For Physicians Increased Potential Access To Opioid Agonist Treatment, 2002-11. *Health Aff (Millwood)*. 2015;34(6):1028–1034.
4. **Calcaterra SL, Bach P, Chadi A, Chadi N, Kimmel SD, Morford KL, Roy P, Samet JH.** Methadone Matters: What the United States Can Learn from the Global Effort to Treat Opioid Addiction. *J Gen Intern Med*. 2019; 34(6): 1039–1042.
5. **Centers for Medicare & Medicaid Services.** National Plan and Provider Enumeration System (NPPES) Downloadable File. <https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/NationalProviderStand/DataDissemination>. Accessed 3 Feb 2020.
6. **Andrilla CHA, Moore TE, Patterson DG, Larson EH.** Geographic Distribution of Providers with a DEA Waiver to Prescribe Buprenorphine for the Treatment of Opioid use Disorder: A 5- Year Update. *J Rural Health*. 2019 Jan; 35(1):108–112. <https://doi.org/10.1111/jrh.12307>.
7. **Fiscella K, Wakeman SE, Beletsky L.** Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder: X the X Waiver. *JAMA Psychiatry* 2018;76(3):229–230.
8. **Potier C, Laprvte V, Dubois-Arber F, Cottencin O, Rolland B.** Supervised injection services: what has been demonstrated? A systematic literature review. *Drug Alcohol Depend*. 2014;145:48–68.
9. **Strang J, Groshkova T, Uchtenhagen A,** et al. Heroin on trial: Systematic review and meta-analysis of randomised trials of diamorphine-prescribing as treatment for refractory heroin addiction. *B J Psychiatry* 2015;207(1):5–14.

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