VIEWPOINT

Overcoming Barriers to Treatment of Opioid Use Disorder

Yngvild Olsen, MD, MPH
Institutes for Behavior Resources Inc, Baltimore, Maryland.

Ruchi M. Fitzgerald, MD
Rush University, Chicago, Illinois.

Sarah E. Wakeman, MD
Massachusetts General Hospital, Medicine, Charlestown.

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Corresponding Author: Yngvild Olsen, MD, Institutes for Behavior Resources Inc, 2104 Maryland Ave, Baltimore, MD 21218 (yngvild.olsen@gmail.com).

On January 14, 2021, days before a change in presidential administrations, the US Department of Health and Human Services (HHS) announced a plan to publish Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder "pursuant to 21 USC §823(g)(2)(H)(i)(II)," a provision of the Drug Addiction and Treatment Act of 2000 (DATA 2000).[1] This announcement caused a mix of enthusiasm, skepticism, and confusion in the medical community, and the retraction of the plan to publish the guideline less than 2 weeks later by the Biden administration has created an opportunity for fundamental and needed reform.

DATA 2000 was a major change in the treatment of addiction. For the first time since 1914, the law allowed physicians to prescribe an approved opioid agonist medication for the treatment of opioid use disorder (OUD) as part of general medical practice, provided these physicians met certain training and practice certification requirements, notified the Substance Abuse and Mental Health Services Administration (SAMHSA), and received approval from the Drug Enforcement Administration (DEA), identified by a separate DEA registration designation (the X-waiver).

Since the passage of DATA 2000, the federal government has made some changes to the law, but its basic infrastructure remains intact. By the end of 2019, 70 020 practitioners in the US had obtained the X designation.[2] However, this number of clinicians has not met pace with need. The opioid overdose crisis continues to evolve and worsen. Preliminary data from the Centers for Disease Control and Prevention found that more than 81 000 deaths related to drug overdose occurred between June 2019 and May 2020, the highest toll yet in a 12-month period.[3] Despite evidence showing that buprenorphine therapy is associated with a decrease in the risk of fatal overdose by 50% or more, from 4.6 to 1.4 per 1000 person-years in one meta-analysis,[4] most eligible practitioners caring for patients with OUD lack the authority to prescribe. As the death count has increased over the last decade, so have calls for substantial, fundamental changes to DATA 2000.

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The intent of the new Practice Guidelines was to usher in these changes. The document purported to enable any physician with a current DEA certificate to prescribe buprenorphine to as many as 30 patients with OUD without any other stipulations. Emergency medicine physicians seemingly would have no limits on the number of patients for whom buprenorphine could be prescribed. The HHS aimed to accomplish this result through an administrative action, not a new law.

However, the Practice Guidelines also included impractical elements and lacked clarity that the stated goals could be achieved. The Practice Guidelines left intact the requirement that physicians notify SAMHSA of their intent to prescribe buprenorphine, shifted the responsibility of identifying the separate DEA designation (X) and treatment indication to the prescribing physician, required recordkeeping of prescriptions issued, and called for maintaining separate medical records for patients treated for OUD. Importantly, the proposed changes applied only to physicians, leaving out nurse practitioners and physician assistants who make up a substantial number of practitioners in high-need areas.

Amidst the background of operational problems, administration turnover, and unanswered questions about the legality of the proposed changes to the DATA 2000 law, the HHS, through the SAMHSA, formally announced on January 27, 2021, that it would not publish the Practice Guidelines.[5]

Despite the limitations of the Practice Guidelines, many were disappointed by the decision not to update the existing law. The main advantage in the proposed action was the elimination of the special 8-hour training required for physicians to receive their X designation from the DEA. Over the years, the separate designation, required training, and administrative burden tied to it have been cited as significant barriers to practitioners adopting effective OUD therapies as a routine part of their practice. Instead, critics have noted that the X-waiver perpetuates the stigma of addiction and its treatments, and uniquely labels addiction treatment as outside of mainstream medicine. Other countries, such as France and Portugal, that lack special training requirements for prescribing buprenorphine have greater access to life-saving care. At the same time, making the provision of care for patients with OUD less burdensome for practitioners is just 1 step toward meeting the growing need for addiction treatment. It is also necessary to close an enormous training gap that leaves many practitioners feeling ill-equipped to treat patients with OUD. Surveys of practicing clinicians report the need for additional educational support as among top barriers to prescribing buprenorphine.[6] Whether recently graduated practitioners have received more than limited training in addiction treatment depends on their school and residency training program, and regardless, the focus must be on those in practice, not trainees.

Among clinicians who have taken the training and obtained their X-waiver, only about 50% make use of it and

when they do, fewer than half prescribe to the maximum number of patients they can.[7] With stigma, prior authorization, and other insurance barriers, as well as reported lack of mental health resources as significant barriers to prescribing buprenorphine, it is possible that implementation of the Practice Guidelines would not have addressed the full range of barriers limiting access to OUD care for patients.

Nonetheless, the sudden appearance and swift demise of the Practice Guidelines has rightly focused attention on the failures of federal policy and the importance of reform. The concepts expressed in 3 key recent proposed pieces of legislation in Congress have the potential to normalize the prevention, diagnosis, and treatment of substance use disorders and simultaneously go a long way toward filling the training gap. Importantly, these ideas could also make significant inroads in reducing the stigma that surrounds substance use disorder treatment and demonstrate that care of patients with these conditions is directly within the purview of the medical community.

The Mainstreaming Addiction Treatment Act would eliminate the special DEA designation policy (X-waiver) along with any unique training requirements for all practitioners and requires HHS to conduct a national education campaign. The Medication Access and Training Expansion Act would add a 1-time, broader educational requirement for all initial or renewal DEA certificate applicants to establish a baseline of knowledge on prevention, treatment, and management of all substance use disorders. This training should also count for continuing medical education hours already required by 39 state medical licensing boards and be at no cost to the DEA applicant. Under the Medication Access and Training Expansion Act, all accredited health professional schools could fulfill the requirement through their own substantial substance use disorder curricula. The Opioid Workforce Act would expand the specialty addiction practitioner workforce by funding 1000 additional graduate medical education slots to qualifying hospitals with approved addiction-focused residency/fellowship programs. These specialists would not only fill needed gaps for care of complex patients, but could serve as consultants and champions for better addiction education and services at their home institutions. It remains unclear whether any of these proposed laws will be enacted and if not, HHS may have to find other approaches to improving the care of patients with OUD.

Ultimately, the goal is to both repeal a policy, DATA 2000, that has long outlived its usefulness and build a sustainable model for practitioner addiction education and training that could improve care and save lives.

ARTICLE INFORMATION

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Conflict of Interest Disclosures: Dr Olsen reported providing direct patient care, including prescribing medications for opioid use disorder, at a nonprofit, ambulatory addiction treatment center in Baltimore, Maryland, and serving as vice president for the American Society of Addiction Medicine and as clinical expert to the Substance Abuse and Mental Health Services Administration–funded Providers Clinical Support System. Dr Wakeman reported receiving personal fees from OptumLabs, Celero Systems, and UpToDate and royalties from Springer. No other disclosures were reported.

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