Removal of DEA makes pharmacists part for treating opioid use disorder

requirement of solution

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What if there were no special steps required of clinicians to help individuals receive medication for opioid use disorder (OUD)? Could this scenario allow patients with OUD to be treated where it's most convenient for them, even in a pharmacy?

After decades of imagining these possibilities, the reality is finally setting in. The Mainstreaming Addiction Treatment (MAT) Act, part of the Consolidated Appropriations Act of 2023 signed by President Biden in late 2022, would remove the requirement for DEA's "X-waiver," which has prevented health care providers, including certain pharmacists, from prescribing buprenorphine for OUD.

The way substance use disorder is viewed—and even taught to pharmacists—has been evolving, according to James Gasper, PharmD.

Changes have been driven by the adoption of a disease state model of addiction, the broader availability of pharmacotherapy, and the pharmacy profession's acknowledgment that addiction in this country is a crisis that requires "all hands on deck" to make a difference, said Gasper, a psychiatric and substance use disorder pharmacist for the California Department of Health Care Service.

"Having the X-waiver removed pushes this one step further and really gives pharmacists in many states the full authority necessary to step up and expand the group of providers who can treat OUD and all other substance use disorders," Gasper said.

In 2022, over 100,000 people died from drug overdoses. More than two-thirds of those deaths involved opioids, primarily fentanyl. Additionally, only 13% of individuals with OUD received evidence-based OUD treatment, like buprenorphine, an FDA-approved opioid agonist/antagonist medication that has been proven safe and effective in treating opioid withdrawal.

To put it another way, roughly 90% of the people with OUD who need and want treatment are not getting it.

Treatment in community pharmacies

A January 12, 2023, research letter published in *NEJM* found that when community pharmacists initiated buprenorphine for patients under CPAs with physicians, patients were more likely to continue their care if randomized to ongoing treatment with the community pharmacists than with a usual, physician-managed care model.

The small study documented the experiences of 100 patients in Rhode Island who started taking buprenorphine after visiting a specially trained community pharmacist for their care. Once stabilized on the medication, 58 patients were randomly assigned to receive either continued care in the pharmacy or usual care in a clinic or physician's office.

After 1 month, patients in the pharmacy care group showed dramatically higher rates of retention: 25 patients (89%) continued to receive treatment in the pharmacy compared to 5 (17%) in the usual care group.

"We thought this would make it easier for patients, but we didn't anticipate this level of engagement," said lead author of the study, Traci Green PhD, MSc, who codirects the COBRE on Opioids and Overdose at Rhode Island Hospital.

The study took place in 6 community pharmacies in Rhode Island that were part of Genoa Healthcare, a provider of specialized pharmacy care for behavioral health and substance use disorder. Pharmacists saw patients in private consultation rooms.

"We got to know the patients, their history, and we tried to see what individualized care they needed," said Andrew Terranova, PharmD, one of the pharmacists from Genoa Healthcare who participated in the study. "Then they could walk out of the pharmacy with the medication right there and then."

Green said patients in some areas of Rhode Island where the study took place would normally have to travel an hour away to get treatment, deal with waitlists, or brave restrictive policies and inflexible scheduling. "It's a long tale of hurdles just to get essential medicine," Green said.

A third of patients in the study identified as Black, Indigenous, or persons of color, and almost half were without a permanent residence.

"We are in an enormous crisis. More pathways to initiate treatment and to stay in treatment is the vision—pharmacy is already the place where the medicine is. People are already there. This provides another whole constellation of treatment points," Green said.

In their study, Green said patients got the attention they needed in the pharmacy. "They knew where to go, and ultimately the medicine works—that part was easy," said Green, who is also a professor at Brown School of Medicine in Providence, RI.

Terranova said the hands-on approach the pharmacists in the study took helped to build a trusting patient-provider relationship and seemed to make it easier for patients to stay on their medication.

"This is a patient population with a chronic disease that needs routine monitoring," said Bethany DiPaula, PharmD, FASHP, from the University of Maryland School of Pharmacy who was not involved in the study. "As pharmacists, we are well-versed in dosing, adverse effects, and monitoring. We can add to the care of patients."

James Gasper, PharmD, said most pharmacists who specialize in treating substance use disorders have worked in institutions or clinic-based settings as part of the treatment team. But community pharmacists, he said, are on the front-line seeing patients struggle daily with opioid problems.

"[Community pharmacists] are accessible for on-demand treatment when someone is ready for it," said Gasper, who is from the California Department of Health Care Service and was not involved in the study. "That level of availability simply doesn't exist today and will no doubt save lives."

He said aspects of treatment, such as short duration prescriptions, frequent refills, and long-term follow up put community pharmacists in a position to have more contact with patients receiving buprenorphine than any other profession.

"The future is bright for us to continue to expand in every practice setting and address addiction like all other chronic diseases," Gasper said. ■

Normalizing treatment

The authority to prescribe controlled substances, including buprenorphine, hinges on a pharmacist's state scope of practice. Currently, 10 states allow pharmacists to prescribe controlled substances. Upon passage of the MAT Act, pharmacists in these states have the ability to prescribe buprenorphine to patients with OUD, depending on collaborative practice agreements (CPAs) and the pharmacist's practice setting within their respective state.

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With the X-waiver requirement removed, all clinicians who hold a DEA license will now be able to prescribe buprenorphine—there will be no differentiating "X" on a prescriber's license.

"From a medical standpoint, we think of the 'X' differently, and this step will hopefully normalize it," said Michelle Geier, PharmD, BCPP, psychiatric clinical pharmacist supervisor at the San Francisco Department of Public Health.

"I hope this will reduce stigma by normalizing treatment for opioid use disorder," said Bethany DiPaula, PharmD, BCPP, FASHP, professor and PGY-2 psychiatric pharmacy residency director at the University of Maryland School of Pharmacy.

Community pharmacists dispensing medication for OUD would not have to verify the prescriber's X-waiver, either.

"It seems like a small thing, but it does help normalize this by using the same process as you would for other chronic diseases," said DiPaula.

A study published August 23, 2022, in *JAPhA* found that most community pharmacists are willing to dispense buprenorphine and have an adequate stock of the medication in their pharmacy. The findings, which were based on a survey sent to almost 7,000 pharmacists nationwide, also demonstrate how policies related to buprenorphine can vary widely in a pharmacy, and how many barriers there are to dispensing.

Pharmacist prescribing of buprenorphine under CPAs has been a goal for pharmacy organizations for years. But the state of California takes it one step further. In January 2023, the California Board of Pharmacy began drafting regulation on a statewide protocol for pharmacists to treat substance use disorder independently, without the need for a CPA requirement.

"This option would not have been able to include evidence-based treatment with buprenorphine access without the removal of the X-waiver," said Gasper. "Once implemented, it is anticipated that these approaches can serve as an example for the other 9 states that allow pharmacists to prescribe controlled substances and potentially serve as encouragement for additional states to add this authority to their pharmacy practice act."

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Training requirements

Geier and her team of pharmacists at the San Francisco Department of Public Health already hold DEA licenses, but when the X-waiver removal news was announced, Geier said each one of them wanted to receive additional training to feel confident in prescribing.

Included in the omnibus spending bill that passed is a provision called the Medication Access and Training Expansion Act which strengthens the training requirement for prescribing controlled substances. The provision will require all clinicians applying for a DEA license to undergo a one-time, 8-hour training course with respect to the treatment and management of patients with opioid or other substance use disorders. Before the passing of the omnibus bill, the training requirement for substance use disorder pertained only to prescribers who could obtain an X-waiver. Now, with the removal of the X-waiver, all prescribers of controlled substances, including pharmacists, are required to complete at least 8 hours of training on substance use disorders.

As this story goes to press, APhA continues to work with HHS' assistant secretary for mental health and substance use to recognize the ACPE in the list of eligible entities that can provide the required training for pharmacists to prescribe buprenorphine.

But the MAT Act alone will not solve all the access issues to buprenorphine. Pharmacists and other clinicians still have to properly prepare and know how to treat individuals with OUD. Stocking and having the medication readily available for patients is necessary.

"Treatment on demand will need to be there," Geier said. "Part of that has to do with making sure pharmacists feel comfortable stocking it and wholesalers are not putting barriers up either. Stigma will continue to need to be addressed, too." ■