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Democracy Dies in Darkness

As drug deaths soar, experts urge expanded access to methadone

Studies show methadone works. But draconian regulations make it hard to get even amid the drug crisis.

By David Ovalle

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Krystal Parker, a former heroin user, spent years making long daily bus trips with other patients to a methadone clinic in southwest Florida. For over a decade, the medication has kept at bay her crippling anxiety and the agonizing nausea of withdrawals.

“When I wasn’t on anything, I couldn’t stand the way I felt in my own skin,” she said. “Methadone satisfies me, but doesn’t get me high.”

But Parker, a 41-year-old mother of three, always fears missing her daily dose. After Hurricane Ian closed her clinic in Port Charlotte last year, she had to pay $100 to a fellow patient for a ride over 40 miles to an open facility. “I was desperate,” she said. Nearby pharmacies had reopened quickly — but by law, only methadone clinics can dispense the drug to treat addiction.

Parker's experiences underscore what critics say are draconian methadone regulations that erect barriers to one of the few effective treatments for opioid use disorder — a life-or-death hurdle that may finally be overcome if Congress acts this year to expand access to the drug. Bipartisan bills were reintroduced in both chambers of Congress late last week that would allow patients seeking treatment to get methadone at local pharmacies with a prescription from a doctor specializing in addiction, in addition to from federally regulated clinics.

Proponents of the measures say methadone is proven to help wean people off more dangerous street drugs, yet remains frustratingly difficult to get — even amid an opioid crisis claiming nearly 300 lives each day. A rigid clinic system imposed 50 years ago often requires daily visits to clinics that critics say stigmatize patients, disrupt lives and make it difficult to work.

The clinics had already begun loosening up due to the pandemic. Apart from the proposed legislation, the federal government is moving to make permanent the relaxation of rules that made it easier for patients to take home doses of methadone.

"You're saving a lot of lives by having people treated with methadone," said Yngvild K. Olsen, director of the Center for Substance Abuse Treatment at the Substance Abuse and Mental Health Services Administration (SAMHSA), one of the agencies that oversees clinics.

But at least one group is not on board with proposals to expand access to methadone beyond the clinic system — the clinics themselves, many of which are for-profit.

Mark Parrino, president of the American Association for the Treatment of Opioid Dependence, the industry trade group, cites a worrisome recent uptick in methadone-related overdose deaths as a warning signal about why it may be dangerous to broadly deregulate methadone — itself an addictive drug that can be used to treat pain.

He believes the legislation, if passed, would probably lead to the diversion of methadone to the streets — with grim consequences. "If that happens, I assure you there will be media accounts of methadone designed to treat opioid use disorder now killing people," Parrino said.

That prediction is dismissed by many addiction specialists and the bills' backers, including Sens. Edward J. Markey (D-Mass.) and Rand Paul (R-Ky.) and Reps. Donald W. Norcross (D-N.J.) and Don Bacon (R-Neb.). They note that methadone can already be prescribed by physicians and dispensed by pharmacies for chronic pain. Amid a raging fentanyl crisis, they argue, board-certified specialists should be able to write prescriptions to treat addiction.

"Our communities are shouldering not just an opioid crisis but also an overdose crisis," Markey said in a statement. "Parents are losing their children. Children are losing their parents. Yet, we are still making recovery harder with outdated rules that burden the very people we need to be providing care for."

'We don't have enough methadone clinics'

Methadone is one of three drugs, including naltrexone and buprenorphine, approved to treat addiction. Buprenorphine is widely used and be can prescribed outside opioid treatment clinics; Congress late last year also made it easier for physicians to treat patients with the drug, which is less potent than methadone.

Methadone, developed as a painkiller for wartime casualties, remains much safer than the illegal street drugs killing tens of thousands of people each year. It blocks the roller-coaster effect of opioids, quashing the cravings coursing through the body. It also stabilizes opioid levels in users who might experience the nausea, chills and sweating of withdrawals from powerful but short-acting opioids such as fentanyl or heroin.

The Food and Drug Administration approved it as a treatment for addiction to heroin and opioids in the early 1970s. But stringent regulations were imposed for fear the heroin epidemic affecting urban Black communities might spill into suburbia, said Paul Joudrey, an assistant professor at the University of Pittsburgh School of Medicine.

"Methadone comes with a lot of historical baggage," said Joudrey, who co-wrote a 2020 study that mapped excessively long drive times to clinics in five states hard hit by opioid deaths.

As a result, Joudrey said, many methadone clinics are in urban areas, even as today's opioid crisis has wreaked widespread havoc across a wide swath of the country.

About 2,000 clinics provide methadone care to at least 300,000 patients, according to federal data — a fraction of the estimated 2.1 million people in the United States with opioid use disorder. In many states, there are just a handful of clinics. Wyoming has zero.

“We don’t have enough methadone clinics,” said Nora Volkow, director of the National Institute on Drug Abuse (NIDA).

Patients in rural areas have the longest commutes, if they can get to clinics at all.

Around Madison County, Ky., hard hit by the drug crisis, that’s prompted an unusual solution — the hiring of four drivers to ferry patients across long stretches of rural areas to a clinic in Richmond, a city about 20 miles south of Lexington. The program, run by the recovery support organization Voices of Hope and funded through NIDA, has logged nearly 200,000 miles over the past year.

Daniel Deatherage, 42, of Harrodsburg, Ky., credits the program with helping him stay stable. A driver picks him up about 7 a.m. for the roughly two-and-a-half-hour round trip. The morning commitment means he must work the graveyard shift, from 5 p.m. to 5 a.m., at an electronics manufacturing plant.

The days are exhausting but worth it. “On methadone, I can live a productive life,” said Deatherage, who struggled for decades with addiction to pain pills, heroin and other opioids.

If pharmacies dispensed methadone, his life might be easier — he lives just a few minute walk from one.

A ‘suspicion of criminality’

For patients involved with methadone clinics, the daily routine can feel like being on probation. Many show up before the sun rises, standing in line, attending counseling and filling out worksheets. They’re watched as they drink a small cup of the red liquid.

“In no other treatment context does a patient enter into a medical intervention with the suspicion of criminality from the onset,” said Erin Fanning Madden, a professor of public health and medicine at Wayne State University in Michigan.

Counseling sessions are mandated. Urine tests are regular. Missing an appointment can lead to a reduction in a dosage of methadone, patients say.

Louise Vincent, a 46-year-old methadone patient in Greensboro, N.C., describes every morning as a scramble. Because she recently had her leg amputated, Vincent's partner carries her to their car for the hurried drive to the clinic, which closes for dosing at 10:30 a.m.

Patients jokingly call the mad dash the "Methadone 500."

"If you're one minute late to many clinics, they lock you out," said Vincent, who is executive director of the North Carolina Urban Survivors Union, which is affiliated with a national group that in 2021 published a "Methadone Manifesto" calling for an end to the clinic system.

For advocates of widening access to methadone, the relaxed rules during the pandemic offered a real-world experiment that they say proved the benefits of giving patients greater control over their lives. In March and April of 2020, as government agencies sought to curb the spread of the coronavirus, SAMHSA loosened regulations on taking home doses of methadone. Clinics had flexibility to give patients deemed "stable" up to 28 days' worth of doses. Patients with less time in treatment and fewer negative drug tests could get up to 14 take-home doses.

One study that looked at five rural counties in Oregon found that stable methadone patients who got more take-home doses had fewer urine samples coming back positive for drugs and felt more trusted. In addition, their reduced travel time "permitted increased employment and recreation."

In December, SAMHSA cited the study in proposing to make permanent the relaxed rules for take-home doses, saying patients "saw positive impacts on their recovery, including being more likely to remain in treatment and less likely to use illicit opioids."

Last week, a group of academics released an analysis of 29 studies that also supported making the rules permanent. "It took a pandemic to break through" long-restrictive methadone rules, it said.

Nonetheless, some experts have urged a cautious approach, noting that although methadone does not offer the same intense high of heroin or fentanyl, it can still be abused, with potentially deadly results.

One group noted that when Denmark loosened restrictions on its use, methadone overdoses increased at the same rate as heroin overdose decreased, “offsetting any public health or safety benefit of the new regulations.”

Such concerns may be born out by U.S. data, although experts say it’s too early to tell.

A review of Centers for Disease Control and Prevention death records shows 3,359 methadone-related overdoses in 2020, when take-home dose rules were relaxed — a 30 percent increase from the previous year, although many of those deaths may have also involved illegal street drugs such as fentanyl. It’s also unclear how many of the overdoses might have involved pain prescriptions. The uptick might not be a blip: Provisional data shows at least 3,528 overdose deaths involving methadone in 2021.

“Accommodations during covid were necessary, but this data suggests we should really be cautious about making these changes permanent,” said Brian Piper, lead author on a study documenting the increased overdoses and an assistant professor of neuroscience at the Center for Pharmacy Innovation and Outcomes at the Geisinger School of Graduate Education in Pennsylvania.

Proponents of deregulation note the number of methadone-related overdoses represents only a small fraction of overall drug overdose deaths, which reached about 107,000 in 2021, the last year for which complete data is available. Given the magnitude of the drug crisis, they argue that if more people with opioid use disorder used methadone, rather than street drugs, there would be far fewer overdose deaths.

“We’re interested in the net outcome,” said Madden from Wayne State. “If there’s an overall decrease in overdoses, that’s a win.”

The view from the clinics

The trade group that represents methadone clinics said it supports SAMHSA’s relaxations on take-home medication. The group’s president says the organization also endorses dispensing from pharmacies — but only if clinic doctors are writing the prescriptions.

“Some patients really want or would prefer to go to a pharmacy like other people who are picking up prescriptions for other chronic illnesses,” Parrino said. “And we understand that.”

But the trade group takes a hard line opposing measures that would allow addiction specialists outside the clinic system to prescribe methadone.

Clinic proponents insist patients need the structure of that system, and contend that its doctors have the greatest expertise in treating opioid use disorder with methadone, particularly in the initial treatment stage when patients could overdose if given too much.

Although the bills introduced into Congress would allow only board-certified addiction specialists to prescribe methadone, Parrino predicts that would lead to more overdoses as some patients sell or give away the drug. “Does anybody really think that the unstable fentanyl-using, heroin-using patient is going to take that 30-day supply home and use it as prescribed?” he asked.

Brian Hurley, president-elect of the American Society of Addiction Medicine, counters that the issue of patients misusing methadone is a “clinical question, not a regulatory one.”

“I trust addiction physicians to be able to evaluate diversion risks and the potential of patients to go off and sell their methadone,” Hurley said. “We have the training to be able to manage that.”

Norcross, a co-sponsor of the House bill, calls industry arguments self-interested, suggesting the “clinic cartel” simply wants to protect its profits. “Many of them are making money by keeping it restrictive,” he said.

For methadone patients such as Parker, of Florida, the push to make methadone available at pharmacies makes sense. Her story illustrates the frustrations and the successes of the methadone system.

She started using pain pills with a boyfriend in her mid-20s, then graduated to heroin before doing her first stint in a methadone clinic. While under court supervision for dealing in stolen property, Parker says, she relapsed after her probation officer wouldn’t let her leave the county to go to the clinic. She ended up going to prison for 17 months.

After her release in 2011, Parker used drugs again, but later returned to a methadone clinic, taking a ride-sharing bus paid for by Medicaid. She didn’t get the benefit of the eventual pandemic-relaxed rules — it took her almost four years to earn the right to take home just a week’s worth of doses.

Now, with her clinic commute down to once a week, Parker said she spends more time working with her boyfriend's lawn care service and caring for her three children, ages 9, 14 and 19. And she runs a Facebook support group, Life on Methadone. Her followers agree methadone rules shouldn't be so tough.

"For those of us who have never been a problem patient, who go out of our way to do things the right way," she said, "we should be granted a little more leniency."

Dan Keating contributed to this report.