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National Academies Workshop on Methadone Regulations

By: Bridget C.E. Dooling | March 16, 2022

In brief…

A recent National Academies workshop on the federal rules governing methadone treatment explored how these rules restrict patient access to life-saving treatment for opioid use disorder. As the overdose epidemic rages on, these regulations need an overhaul. Recent research from the Regulatory Studies Center, with support from the Pew Charitable Trusts, sheds light on promising pathways for reform.

Overdose deaths continue to rise at alarming rates in the United States. Opioid-related overdoses are one part of this larger and disturbing trend. Methadone is one of three approved medications that can be used for the treatment of opioid use disorder, and it is effective at reducing overdose deaths. Unlike other forms of medical treatment, methadone is subject to a raft of regulatory requirements that control who can receive treatment, who can provide treatment, when, how often, and in what manner. This unusual set of requirements is one reason why "methadone clinics" exist as standalone health care providers. It's also why patients have to queue up at these clinics almost every day to obtain their daily dose.

The National Academies of the Sciences, Engineering, and Medicine (NASEM) convened a two-day workshop to take stock of the federal statutes and regulations that apply to methadone treatment for opioid use disorder. I was honored to be on the planning committee for this workshop and also a presenter on the first day. This workshop grew out of a NASEM project on methadone regulations sponsored by the U.S. Office of National Drug Control Policy, which is part of the Executive Office of the President and coordinates policy issues surrounding drug policy.

In my talk I emphasized the importance of the difference between statutes and regulations. As policymakers and advocates try to determine which of the existing rules should change, it's important to understand whether the underlying statute needs to change, or whether federal agencies can make the change administratively through rulemaking. It's not enough to ask a federal agency to change something that only Congress can change; better to direct those efforts to Congress. And it's a missed opportunity if

we fail to recognize places where Congress has given an agency authority to provide flexibilities that it's not using.

This distinction was central to two recent reports that I co-authored with Laura Stanley, Senior Policy Analyst at the Regulatory Studies Center. In these reports, developed with support from the Pew Charitable Trusts, we evaluated whether certain pandemic-related treatment flexibilities for opioid use disorder could be extended beyond the pandemic. One of these reports was about additional flexibility around take-home supplies of methadone, to help keep people home and safe and in treatment rather than coming to the clinic to pick up their dose.

As noted above, most methadone patients must come to their methadone clinics (or, as the regulations call them, "opioid treatment programs") almost every day to collect their dose. While there are opportunities for a take home supply, meaning a batch of doses that a patient can bring home for multiple days, those opportunities are the exception, not the rule. This is because the regulations (but not the statute) require it to work this way. Early in the pandemic, the Substance Abuse and Mental Health Services Administration (SAMHSA), which is part of the U.S. Department of Health & Human Services, explained in guidance that states could request flexibility to allow "stable" patients in an opioid treatment program to receive 28 days of doses at once. The state could also request up to 14 days of take-home doses for "less stable" patients at the opioid treatment program's discretion.

Advocates have long pushed to make it easier for patients to have take-home supplies because daily clinic trips are very disruptive, especially if clinics are not close to home. The pandemic profoundly shifted the sands, and SAMHSA opened up this lane for patients to access their medication more easily. Understandably, some were concerned that when the pandemic ends, the flexibility would end, too. SAMHSA could retract this guidance just as easily as it was issued. Guidance isn't "sticky" or "durable" in the sense that you can rely on it long-term.

Laura and I wrote our reports to get to the bottom of whether that flexibility was required by law to end, or whether removing it was merely a policy choice. Our findings were stunning. We found that SAMHSA has ample authority to embed take home flexibilities in its regulations, without needing additional statutory authority. And, the agency seems to have agreed! The Biden administration announced its intention to issue a rule to make the take home flexibilities last beyond the pandemic.

Laura and I are in the initial stages of an additional project to look more closely at methadone regulations, beyond the take-home provisions. More soon on that project and its findings. In the meantime, the workshop video will soon be available on the workshop website. The full agenda is a roadmap to two days of engaging talks about this topic from those with personal experience with methadone treatment, government leaders, public health researchers, medical practitioners, lawyers, and other academics.