are likely to persist in the absence of massive efforts on multiple fronts. The dynamics by which high prices rewarded manufacturers, insurers, and PBMs still exist for some insulin products and for other medications. Although Americans continue to be willing to pay for new drugs — as is evident in the lag between FDA approval of a drug and when Medicare can implement negotiated prices under the Inflation Reduction Act (9 and 13 years for small-molecule and biologic drugs, respectively) — patience with paying high prices for older drugs is wearing thin. A possible silver lining of this lengthy and painful episode in U.S. drug history is that high, oligopolistic pricing will most likely be harder to sustain for mass-market products that have therapeutic substitutes and for which copycats can be made relatively easily. If that sounds like qualified, muted applause, it is. But it is applause nonetheless.

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Beyond the X — Next Steps in Policy Reforms to Address the Overdose Crisis

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According to the National Center for Health Statistics, 2021 was the deadliest year on record for the drug-overdose crisis. The end of 2022, however, was marked by a long-awaited policy change that could help reverse the trend of increasing overdose deaths. As part of the Consolidated Appropriations Act, the federal government eliminated the "X waiver," a regulatory barrier that had impeded clinicians' ability to offer lifesaving buprenorphine treatment for opioid use disorder (OUD). The X waiver limited buprenorphine privileges to prescribers who opted to get a special license from the Drug Enforcement Administration (DEA) and underwent uncompensated training. Such prescribers were subject to random audits and faced caps on the number of patients they could treat with buprenorphine. This policy enshrined a mistaken notion of buprenorphine treatment as more complicated and riskier than other types of medical care and contributed to stigma against people with OUD.[1] The change allows any prescriber with a general DEA license — which is required to prescribe any controlled substance — to offer buprenorphine, thereby aligning addiction treatment with the approach to other health conditions. At long last, the X has been "X'ed."

But positive public health effects of this reform aren't guaranteed. The federal government has already announced an additional requirement of an 8-hour addiction-related training for prescribers of controlled substances, including buprenorphine. This education will be required for practitioners applying for or renewing their DEA registration, with the exception of physicians with addiction-related specializations and various practitioners who graduated since 2018 from schools with comprehensive addiction curricula.

Some options are provided for meeting this requirement, including a flexible training format, source, and time of completion. Even so, we believe imposing any

new, onerous requirements on an overstretched workforce is problematic. Clinicians have become increasingly hesitant to prescribe controlled substances, and more patients would be harmed if prescribers opted out of getting a DEA license altogether. We believe a more sensible long-term alternative would be to require education on addiction treatment in medical schools, residency programs, and other training programs as a core component of the curriculum so that all future practitioners will have met this requirement during their training. Curriculum changes could be spurred by medical boards adding questions to existing licensing exams; leading medical-education organizations, such as the Association of American Medical Colleges, mandating the teaching of such content; or the Accreditation Council for Graduate Medical Education adding addiction-medicine education to its core program requirements.

In addition to federal requirements, some states have proposed establishing training requirements or other restrictions that go beyond this new framework. For example, Alabama has suggested imposing stricter rules on buprenorphine treatment, which would involve mandating more frequent visits, not allowing concurrent treatment for patients taking some psychiatric medications, and requiring counseling during treatment. The scientific rationale for these interventions is unclear; at least in some jurisdictions, misinformation may drive state policymakers to erect new — and more onerous — barriers even as federal hurdles are being dismantled.

The impending end of the Covid-19 public health emergency and the potential rollback of telemedicine flexibilities — which have expanded access to buprenorphine treatment — also pose a threat to access. Although the DEA has proposed continuing to allow audio-only telemedicine for buprenorphine treatment, a new draft rule would also require an in-person visit within 30 days after medication initiation. Such a requirement could make treatment inaccessible, since health care systems are still recovering from the pandemic and patients can sometimes wait months to get an in-person appointment.

We believe eliminating the X waiver is necessary but not sufficient to achieve overdose-prevention goals. Further action will be especially critical given worsening racial and ethnic disparities, with the largest relative increases in overdose deaths occurring among Black people and American Indian and Alaska Native people, according to the Centers for Disease Control and Prevention. Additional reforms are necessary to facilitate adoption of OUD treatment by prescribers and to address other barriers. The X waiver was one example of an onerous and unnecessary barrier to a lifesaving intervention, but there are many others, including methadone regulations and policies obstructing access to harm-reduction services.

Methadone use, like buprenorphine use, is associated with reduced overdose-specific and all-cause mortality.[2] Unlike many other countries, where physicians prescribe and pharmacies dispense methadone, the United States has maintained regulations that limit the dispensing of methadone to opioid-treatment programs (OTPs). This policy carves out some forms of OUD treatment from the medical system, requires patients to visit an OTP daily for months or years before receiving medication to take at home, and because of a "not in my backyard" sentiment, often means that patients must wait in line at clinics located in neighborhoods that are challenged by poverty, public drug use, and crime.

The location of OTPs has had important ramifications. First, it has created a racist, two-tiered system in which buprenorphine is more available to White and affluent communities and methadone treatment is concentrated in Black, Latinx, and impoverished communities.[3] Second, it requires people trying to obtain OUD treatment to make daily visits to areas that may be associated with active drug use, thereby increasing the risk of recurrent use. Third, it conflates in the public's mind methadone treatment with chaotic drug use that may be visible in the same geographic area. For example, in Boston, the derogatory label "methadone mile" has been given to an area affected by open-air drug use and homelessness that is also home to two OTPs. Finally, there are profound regional variations in access to methadone, with rural areas often having vast treatment deserts. A recent study found substantial variation in the number of OTPs relative to state populations, ranging from none in Wyoming to 2.1 per 100,000 residents in Rhode Island.[4]

We believe the federal govern-

ment should continue its important progress in expanding access to medication for OUD by rethinking methadone regulations. Methadone treatment models that are more patient-centered and better facilitate access are the norm in many countries. Critics of changes to methadone regulations cite concern about methadone overdose as a reason to maintain the status quo. Despite the benefits of methadone use, there is an increased risk of overdose during the induction period. It's possible that this increased risk is a result of ongoing use of other opioids because of slow upward adjustment of methadone doses, but methadone's pharmacokinetics may also mean that greater caution is required during the initiation phase.

Data collected since the onset of the Covid-19 pandemic — during which expanded and more flexible take-home methadone dosing was allowed — showed improved patient experience and treatment retention without clear evidence of increased methadone-related overdose, which supports potential reforms.[5] A first step to expand access while addressing concern about overdoses could be to allow patients stabilized by means of treatment at an OTP to transition to office-based care with general practitioners and to permit physicians specializing in addiction medicine or addiction psychiatry to initiate and provide ongoing methadone treatment. Federally qualified health centers could also serve as critical access points for methadone.

In addition, several policy changes and financial investments could help ensure that all people at risk for overdose can receive the treatment and harm-reduction services they need. Sustained federal funding is needed for training programs, including for addiction-medicine and addiction-psychiatry fellowship positions; programs allowing nurse practitioners, psychologists, social workers, and mental health counselors to receive specialty training in addiction; and programs supporting general practitioners in providing addiction care. Giving incentives for health systems to offer integrated and low-barrier treatment by creating funding opportunities, implementing related quality measures, and adding accreditation requirements could help ensure the adoption of evidence-based care. Finally, policies and funding to support harm-reduction programs — such as policies permitting federal funding to be used for syringe-access programs; funding to expand drug-checking services, which allow people to test the composition of drugs to reduce overdose risk; and legalization of and funding for overdose-prevention sites — are necessary.

The X waiver was a massive hurdle to providing addiction-treatment services that has now been eliminated. We believe it's necessary to continue this progress and push for additional changes to expand methadone access, invest in the addiction-treatment workforce, provide incentives for health systems to offer addiction treatment, and scale up harm-reduction programs.

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