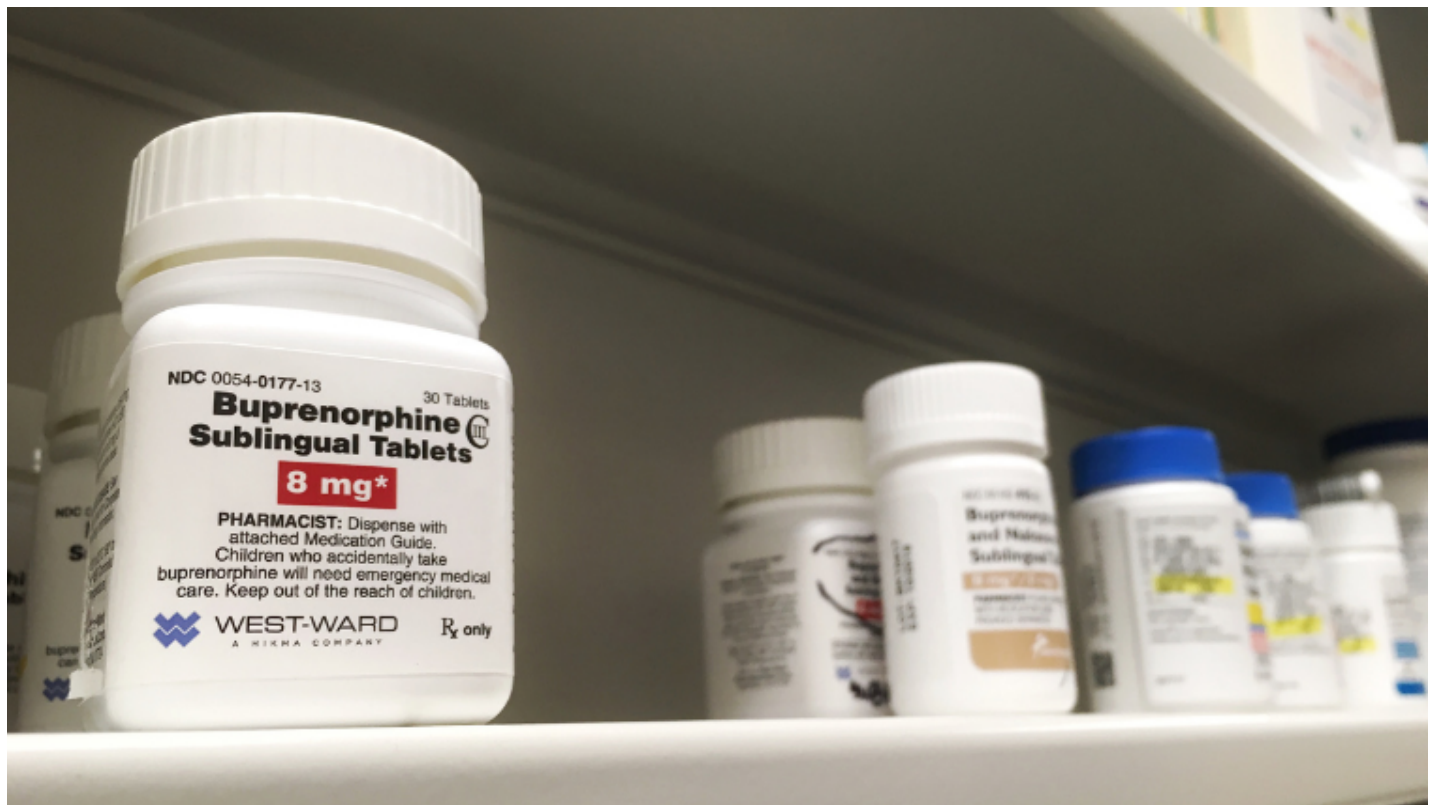


# Removing The X-Waiver Is One Small Step Toward Increasing Treatment Of Opioid Use Disorder, But Great Leaps Are Needed

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Buprenorphine treatment is among the most effective options for people with opioid use disorder (OUD), but it remains underutilized. Increasing buprenorphine treatment receipt is [one of the most reliable ways](#)

<http://www.ncbi.nlm.nih.gov/pubmed/28446428> to reduce opioid overdose deaths.

Currently, the treatment of OUD with buprenorphine in outpatient settings is restricted to clinicians receiving an “X-waiver” under the Drug Addiction Treatment Act of 2000.

To receive this waiver, qualified clinicians must attend [waiver training sessions](#)

<https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine->

[waivered-practitioner](#)> for eight hours; other eligible practitioners, including nurse practitioners and physician assistants, must attend an additional 16 hours of training. Clinicians must then submit a Notice of Intent to the Substance Abuse Mental Health Services Administration before they can begin prescribing; in some states, non-medical doctors must also have a [qualified supervising physician](#)  [<https://www.asam.org/advocacy/practice-resources/buprenorphine-waiver-management>](https://www.asam.org/advocacy/practice-resources/buprenorphine-waiver-management) .

In the closing days of the Trump administration, the Department of Health and Human Services issued guidance relaxing the X-waiver requirement. Given the years-long push to “[X the X waiver](#)  [<https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2719455>](https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2719455),” this modest change was hailed by some advocates as removing what they viewed as a [major barrier to providing treatment](#). Due to legal and operational problems, the Biden administration rescinded this guidance shortly after taking office; nonetheless, X-waiver reform remains under consideration, with the Biden-Harris administration naming “[remove unnecessary barriers to prescribing buprenorphine](#)  [<https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf>](https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf)” in its statement on drug policy priorities. But removing the X-waiver is only a small step in an area where great leaps are needed.

To be clear, it should not be harder for clinicians to prescribe buprenorphine for OUD than it is to prescribe the same medication for pain (for which no special training is required), or for that matter to prescribe oxycodone. But X-waiver reform has minimal potential to increase treatment receipt or reduce opioid overdose deaths. Reforming or removing the waiver altogether could have some benefits at the margin, but a meaningful increase in treatment receipt requires removing other, more significant barriers to treatment.

### Three Challenges Of X-Waiver Reform

First, the X-waiver requirement is not what prevents most clinicians from prescribing buprenorphine. Among non-waivered clinicians, regulations such as the waiver are [the least common barrier](#)  [<https://pubmed.ncbi.nlm.nih.gov/25651434/>](https://pubmed.ncbi.nlm.nih.gov/25651434/) to prescribing buprenorphine, and a full third of non-waivered clinicians report “[nothing will increase \[their\] willingness](#)”  [<http://www.ncbi.nlm.nih.gov/pubmed/28554597>](http://www.ncbi.nlm.nih.gov/pubmed/28554597) to increase prescribing. The resources that would most increase their prescribing, in contrast, include [mentorship and more education](#)  [<http://www.ncbi.nlm.nih.gov/pubmed/28554597>](http://www.ncbi.nlm.nih.gov/pubmed/28554597) about OUD.

More commonly cited barriers among waived and non-waived clinicians alike include [inadequate training <https://pubmed.ncbi.nlm.nih.gov/25651434/>](https://pubmed.ncbi.nlm.nih.gov/25651434/), [lack of confidence in treating OUD, and limited access to addiction experts <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2219773/>](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2219773/). Other barriers [include <http://link.springer.com/10.1007/s11606-020-06257-4>](http://link.springer.com/10.1007/s11606-020-06257-4) stigma, low patient demand, too little clinician time, inadequate reimbursement, and limited access to psychosocial support and services.

Second, even overcoming the hurdle of obtaining the waiver is not enough to promote prescribing. Half of waived clinicians [do not prescribe at all <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769683>](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769683), and among prescribing clinicians, the aforementioned barriers have imposed a de facto capacity limit far below the de jure limit of 30 allowed the first year: From 2017 to 2019, the median number of patients treated monthly [was only 8.3 <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769683>](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769683). Removing the waiver will not support initiating, continuing, or increasing buprenorphine prescribing among those already waived.

Finally, the French experience with buprenorphine [deregulation <https://pubmed.ncbi.nlm.nih.gov/17915074/>](https://pubmed.ncbi.nlm.nih.gov/17915074/) that has been widely cited (for example, in this [viewpoint <https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2719455>](https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2719455)) does not clearly generalize to the US. The scale of the achievement reached there ([estimated to translate <https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2719455>](https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2719455) to a 50 percent annual decrease in overdose deaths [compared to 2020 <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>](https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm)) is [not anticipated in the US <https://pubmed.ncbi.nlm.nih.gov/33587136/>](https://pubmed.ncbi.nlm.nih.gov/33587136/) with even the most ambitious change. Indeed, [France's success <https://pubmed.ncbi.nlm.nih.gov/17915074/>](https://pubmed.ncbi.nlm.nih.gov/17915074/) occurred in the context of a very different medical system, including a universal coverage health care system that fully reimburses OUD clinicians, provides free health care and psychosocial support to patients, and allows for buprenorphine dispensing at pharmacies. The US health care system shares none of these features. Removing regulations might have simply removed the last remaining barrier to buprenorphine treatment in France, rather than removing one of many.

## Other Policies Would Increase Buprenorphine Receipt More

As the Biden Administration develops its strategy to address the substance use disorder (SUD) crisis, it should consider policies targeting clinician-level barriers that will have a

greater impact on buprenorphine receipt than would removing the X-waiver. Here, we focus on just three that are among the [more frequently cited](http://link.springer.com/10.1007/s11606-020-06257-4) [barriers to prescribing to more people](http://link.springer.com/10.1007/s11606-020-06257-4): reimbursement, prior authorization, and education/training.

Reimbursement barriers [can be broken down](http://link.springer.com/10.1007/s11606-020-06257-4) [into concerns about adequacy as well as stability](http://link.springer.com/10.1007/s11606-020-06257-4). Regarding adequacy, Medicare and Medicaid should cover medication for opioid use disorder (MOUD) with sufficient reimbursement rates to attract clinicians, and federally operated health care systems should comparably resource these treatments. The Mental Health Parity and Addiction Equity Act ([Public Law 110-343](https://www.congress.gov/110/plaws/publ343/PLAW-110publ343.htm) <https://www.congress.gov/110/plaws/publ343/PLAW-110publ343.htm>) can simultaneously be enforced to ensure the same financial support from private insurance companies. Regarding stability, time-limited grants to states, which have been the mainstay of OUD funding in recent years and substance use disorder (SUD) funding for decades, not only fail to remove this barrier but actually exacerbate it. By creating a separate funding stream outside of mainstream insurance, block grants worsen the current detachment of the SUD treatment system from the rest of health care. If the goal is to treat SUD like we treat other chronic health conditions, then [reimbursement should be restructured](https://europepmc.org/article/med/33493325) <https://europepmc.org/article/med/33493325> to permanently integrate SUD care into mainstream insurance mechanisms.

Other insurance reforms include curbing prior authorization requirements, which in one study was the [most common barrier cited](https://pubmed.ncbi.nlm.nih.gov/28132694/) <https://pubmed.ncbi.nlm.nih.gov/28132694/>, and service limitations set by insurance companies. Removing these barriers could free up clinician time and [enable them to treat more patients](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764598) <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764598> as well as increase the success of MOUD treatment by reducing delays to first dose.

Lack of training, knowledge, and low confidence in treating OUD are [formidable barriers](https://pubmed.ncbi.nlm.nih.gov/31766053/) <https://pubmed.ncbi.nlm.nih.gov/31766053/> to prescribing buprenorphine that, ironically, could be exacerbated by removing the waiver requirement. New [training and education requirements](https://www.nejm.org/doi/full/10.1056/NEJMp1802741) <https://www.nejm.org/doi/full/10.1056/NEJMp1802741> for students and residents would build our future workforce. To retrain the current workforce, one approach could be to require all clinicians to document training in SUD, including the potential of some medications to be addictive, prior to letting them receive or renew their Drug Enforcement Administration license to prescribe controlled drugs. Such an approach would greatly incentivize all clinicians, and not just those who intend

to treat SUD, to have SUD training if they are to continue practicing. This could have the added benefit of reducing unnecessary prescribing of high-risk medications.

Finally, removing the waiver and other regulations could eventually reduce the significant [stigma <https://bmcfampract.biomedcentral.com/articles/10.1186/s12875-019-1047-z>](https://bmcfampract.biomedcentral.com/articles/10.1186/s12875-019-1047-z) toward people with OUD and buprenorphine itself, as others have [suggested <https://www.nejm.org/doi/full/10.1056/NEJMp1802741>](https://www.nejm.org/doi/full/10.1056/NEJMp1802741). But removing the waiver requirement is a [limited strategy for reducing stigma <https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2719455>](https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2719455) because it is the stigma of addiction itself that led to its special status in the first place, as a medication used to “[cater to the appetite or satisfy the craving <https://www.law.cornell.edu/supremecourt/text/254/189>](https://www.law.cornell.edu/supremecourt/text/254/189)” of an addicted person, as one US Supreme Court opinion put it. However, fully [integrating and financially supporting SUD care <https://europepmc.org/article/med/33493325>](https://europepmc.org/article/med/33493325) would also improve OUD care quality and accountability while also reducing stigma.

In sum, X-ing the X waiver removes an individual-level barrier facing clinicians but does not represent structural change. As such, it is a worthwhile reform with no foreseeable harms but with only modest benefits. Political capital is a limited resource that should be targeted toward reforms that are most likely to have sustainable and large impact. The Biden administration should go far beyond X-waiver reform to transform the structure of health care delivery to people with SUD. Through a combination of policies targeting federal and private insurance clinicians and retraining the medical workforce, we could dramatically improve treatment access and quality while also reducing stigma toward OUD and buprenorphine, as well as integrate all SUD treatment within the mainstream health care system.

## Article Metrics



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