

# A Last-Minute Attempt to Partially X the X Waiver

By: Laura Stanley | February 3, 2021

## In brief...

The Trump administration made a last-minute attempt to provide flexibilities for prescribing buprenorphine to treat opioid use disorder. The Biden administration changed course and decided not to publish the associated guidelines due to legal and policy concerns. Although HHS appears to have the legal authority to provide exemptions from buprenorphine requirements, taking time to ensure flexibilities are legally defensible will promote the uptake of the policies in the long term.

In a decision released less than a week before the end of the Trump administration, the Department of Health and Human Services (HHS) announced a major change to the policy for prescribing buprenorphine to treat opioid use disorder. HHS released a prepublication version of [guidelines](#) that would allow physicians to treat a limited number of patients with buprenorphine without first obtaining a waiver from HHS. The guidelines were submitted to the Federal Register but not yet published. The Biden administration changed course and [decided not](#) to publish the guidelines due to “legal and clinical concerns.”

## Buprenorphine and the X Waiver

Buprenorphine is one of two drugs that are considered the [gold standard](#) for treatment of opioid use disorder. It alleviates the painful withdraw symptoms associated with stopping opioid use. Prior to the Drug Addiction Treatment Act of 2000 (DATA 2000), a practitioner could only prescribe and dispense buprenorphine to patients at federally certified opioid treatment programs. Opioid treatment programs must comply with burdensome regulations issued by the Drug Enforcement Administration (DEA) and HHS. In an effort to expand access to treatment, DATA 2000 “waives” practitioners from these opioid treatment programs regulations and allows them to prescribe buprenorphine to patients, but only if they meet certain requirements. To obtain the “X waiver,” practitioners must take an 8-hour course with HHS and follow restrictions regarding the number of patients they can treat at a time.

Although the requirements for the X waiver are less onerous than the regulations for opioid treatment programs, the requirements still make it difficult for practitioners to obtain the waiver and act as an unnecessary barrier to providing opioid treatment with buprenorphine. Public health advocates have [criticized](#) these requirements for years, pointing out that few practitioners are licensed to prescribe buprenorphine and that the X waiver is a significant obstacle. There is evidence that reducing the requirements for prescribing buprenorphine can lead to increased patient treatment and decreased

overdose deaths. For example, in the four years following France’s change in policy to allow all doctors to prescribe buprenorphine without additional licensing, overdose deaths in the country [declined](#) by 79 percent and number of individuals with opioid use disorder that received treatment increased by more than 95 percent.

## Guidelines Exempting Physicians from the X Waiver Requirements

On January 14, 2021, HHS announced a forthcoming policy that would allow physicians to treat a limited number of patients with buprenorphine without first obtaining an X waiver from HHS. It released a prepublication version of the “Practice [Guidelines](#) for the Administration of Buprenorphine for Treating Opioid Used Disorder.”

Under the existing HHS regulations, any “[qualified practitioner](#),” including physicians, nurse practitioners, and physician assistants, can obtain an X waiver. Qualified practitioners who obtain a waiver can treat up to 100 patients in the first year and 275 patients after the first year. The guidelines, though, only created partial exemptions from the X waiver requirements. The guidelines extended only to physicians, and physicians were limited to treating 30 patients in total at a time with buprenorphine.

HHS submitted the guidelines to the Federal Register but they were not published before the Biden administration took over. The Biden administration changed course and [decided not](#) to publish the guidelines partially due to legal concerns.

## Does HHS have the Legal Authority to Exempt Physicians from X Waiver Requirements?

In the guidelines, HHS argued it has the legal authority to “create exemptions from certification requirements...by issuing practice guidelines pursuant to [DATA 2000].”

The [statute](#) at 21 U.S.C. § 823(g)(2)(H)(i)(II) does give HHS the authority to create exemptions from the X waiver requirements:

In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address...additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

“Paragraph” refers to 21 U.S.C. § 823(g)(2), which lays out the requirements practitioners must follow to obtain an X waiver.

Although HHS appears to have authorization from Congress to provide flexibilities from the X waiver requirements by issuing guidelines, it is not apparent that the Trump administration followed the directions from Congress in the process of creating the guidelines. Congress told HHS to consult the other agencies that have a stake in the outcome of the policy, including DEA, SAMHSA, and FDA, prior to releasing guidelines. If HHS consulted with these agencies, it did not include any record of the discussions in the guidelines. Given the last-minute release of the guidelines, in combination with the Trump administration’s track record of [failing](#) to comply with other procedural directions from Congress, it might be unsurprising to find out the requisite consultations did not take place.

## HHS Should Reduce Requirements for the X Waiver, but HHS Should Comply with Procedural Requirements

Reducing X waiver requirements, or eliminating the X waiver requirements entirely, should be a top priority of the Biden administration. The [majority](#) of physicians do not currently have an X waiver, leading to treatment gaps in many parts of the country, particularly in rural areas. Advocates [argued](#) the guidelines did not go far enough because the flexibilities did not extend to nurse practitioners and physician assistants. Removing the licensing requirements for all relevant practitioners will reduce the barriers for providing buprenorphine treatment and likely increase patient access to treatment and reduce overdose deaths.

Although policy changes to promote buprenorphine access are critical, the Trump administration's hasty release of the guidelines could have failed to do much good. There are downsides if an agency moves too quickly to release a policy through guidance, particularly if there is uncertainty regarding its legal authority and the agency does not comport with important procedural safeguards, like going through the interagency review process at the Office of Management and Budget (OMB).

According to [Washington Post](#) sources, HHS did send the guidelines through interagency review with OMB. When HHS released the prepublication version of the guidelines, Executive Order [13891 \(EO 13891\)](#) was still in place, which required agencies to send their significant guidance documents through notice-and-comment and interagency review with OMB. Although failing to comply with an executive order does not in and of itself create legal vulnerabilities, sending a high-profile guidance document through interagency review helps reduce legal vulnerabilities. Although EO 13891 is [no longer](#) in place, some agencies sent significant guidance documents to OMB for review prior to the executive order and are likely to continue to do so. The interagency review process gives OMB attorneys, as well as attorneys with subject matter expertise from agencies like DEA, the chance to review the guidance for vulnerabilities. OMB review of significant guidance documents also protects against inconsistent or overlapping policies and helps ensure policies do more good than harm. It is even possible that through the interagency review process, HHS might be able to consult with DEA in a manner that complies with the statute, though earlier collaboration is likely even more beneficial.

The Biden administration is not wrong to express concern about HHS' legal authority to issue such guidelines. Public health attorneys [expressed doubt](#) that the statute authorized HHS to take this action. Although the statute appears to give HHS some flexibility, it is not clear if the agency complied with the statutory direction to consult with other agencies in the process of releasing the guidelines. If physicians are under the impression that a policy is legally flawed, they might hesitate to take advantage of the policy knowing it could be challenged. Physicians might be reluctant to begin treating a patient with buprenorphine knowing they might have to pull the rug out from under the patient if the policy changes. Additionally, states might be hesitant to expend resources adopting the flexibilities knowing the policy at the federal level might not withstand legal scrutiny.

The Biden administration [signaled](#) its intent to increase access to buprenorphine and other medication-assisted treatments for opioid use disorder. These policy changes could not come quickly enough. Overdose deaths rose during the pandemic, with some states [experiencing](#) the highest rates of overdose deaths they have seen since the opioid epidemic began. However, taking the time to ensure HHS follows the requisite procedures and the policy changes are legally defensible will promote the uptake of the policies by practitioners and states.