

HHS Eases Requirements for Treating Opioid Patients with Buprenorphine

By: Laura Stanley | May 19, 2021

In brief...

The Department of Health and Human Services recently released guidelines that make it easier to prescribe buprenorphine to patients with opioid use disorder. It withdrew an earlier version of the policy to fix legal vulnerabilities and procedural issues.

One of the Biden administration's top priorities is [reversing](#) elements of the Trump administration's regulatory agenda. It was no surprise that Biden [eliminated](#) the one-in, two-out policy on regulations on his first day in office. But it may be surprising that the Biden administration revoked and then revived a last-minute attempt by the Trump administration to make it easier for practitioners to treat patients with opioid use disorder.

The country faces a worsening opioid crisis. Early estimates suggest there may have been over [90,000](#) drug overdose deaths last year. Yet practitioners face regulatory [barriers](#) to treating patients with buprenorphine, one of the drugs considered the gold standard for treating opioid use disorder. This leads to a dearth of available practitioners and leaves patients without access to the lifesaving medication.

The Biden administration [signaled](#) its intent to remove unnecessary barriers to buprenorphine treatment, and it is already making good on that promise. The Department of Health and Human Services (HHS) recently issued "Practice [Guidelines](#) for the Administration of Buprenorphine for Treating Opioid Use Disorder," which make it easier for practitioners to prescribe buprenorphine to patients. An earlier version of the policy was announced in the last week of the Trump administration, but HHS withdrew that version before it went into effect so it could fix several legal and procedural vulnerabilities.

Practice Guidelines Easing Buprenorphine Prescribing

The Drug Addiction Treatment Act of 2000 (DATA 2000) requires practitioners to obtain an "X waiver" from HHS before prescribing buprenorphine to patients with opioid use disorder. To obtain a waiver, practitioners must take an 8-hour course, submit a notification to HHS, and follow restrictions regarding the number of patients they can treat at any given time. Practitioners, though, can prescribe oxycodone

and other opioids for pain management without any special waiver from HHS. For years, public health advocates have [pointed](#) out that few practitioners are licensed to prescribe buprenorphine, partially due to the obstacles of obtaining an X waiver.

DATA 2000 also [gives](#) HHS the authority to create exemptions from certain X waiver requirements through guidance. The recent HHS practice guidelines rely on this statutory authority and give practitioners the option to obtain a waiver without first completing the 8-hour training course. The similar policy drafted by the previous administration only applied to physicians, but the final guidelines extend this flexibility to additional practitioners, including physician assistants and nurse practitioners. Practitioners who use this flexibility are limited to treating 30 patients at a time, even though practitioners who complete the training course can treat up to 275 patients after their first year.

Practitioners who want to take advantage of this flexibility will still have to submit a notification to HHS and obtain a waiver from the agency. This is legally significant, as the Biden administration [argued](#) the guidelines drafted by the previous administration removed the X waiver altogether, which is not permitted under the statute.

The Biden administration cited lack of approval from the Office of Management and Budget (OMB) as one of the reasons it withdrew the previous administration's guidelines, but this time around the guidelines went through interagency [review](#) at OMB. Failure to send a guidance document through interagency review does not create any legal vulnerabilities itself, but this review process is critical because it gives attorneys and subject matter experts at other agencies, like the Drug Enforcement Administration (DEA), the opportunity to provide input on the guidance. Importantly, DATA 2000 *requires* HHS to [consult](#) with DEA, and although the guidelines do not specify whether HHS completed these consultations, the OMB interagency review process would probably be sufficient to meet this statutory requirement.

HHS Should Consider Notice-and-Comment

The guidelines were a big step forward in expanding patient access to buprenorphine, but the Biden administration should consider issuing this flexibility through notice-and-comment rulemaking to increase its durability. The existing guidelines could be revoked by a new administration with relative ease and speed, and this uncertainty may discourage states and practitioners from adopting the flexibility.

Issuing regulations would be resource and time intensive, but it would give HHS the opportunity to consider expanding the flexibility even further. For example, HHS could accept public comment on extending the flexibility to practitioners who treat more than 30 patients, or to additional [practitioners](#) like emergency department physicians.

Overall, the general sense of continuity across the administrations on this policy indicates there may be rare bipartisan support for reform of regulations that inhibit opioid use disorder treatment. This administration also [plans](#) to finalize other rules conceived under previous administrations that will increase patient access to opioid treatment, including rules that will allow for mobile clinics and increase telemedicine.