

Eliminating the X-Waiver Requirements for DEA-Registered Physicians Prescribing Buprenorphine – To Be or Not to Be?

January 28, 2021

Overview

On January 14, 2021, the US Department of Health and Human Services (HHS) announced new, relaxed guidelines that will permit DEA-registered physicians to prescribe buprenorphine to a limited number of patients without first obtaining an x-waiver. The change is designed to expand access to medication assisted treatment (MAT) by increasing the number of providers authorized to deliver it.

On or about January 27, 2021, the Biden administration effectively cancelled the HHS action, calling for more time to review. The White House drug policy officer stated the X waiver announcement was premature and the Guidelines cannot be issued "at this time."

<https://www.washingtonpost.com/health/2021/01/27/biden-kills-buprenorphine-waiver/>

New HHS Practice Guidelines - January 14, 2021

The Drug Addiction Treatment Act of 2020 restricts when and how a practitioner qualifies to treat patients with buprenorphine. According to the statute, an “x-waiver” or a “DATA waiver” authorizes practitioners to offer MAT to opioid use disorder patients. To obtain an x-waiver, physicians must notify SAMHSA and undergo eight hours of training. 21 U.S.C. § 823(g)(2).

On January 14, 2021, HHS announced that its “[Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder](#)” (the Guidance) created an exemption from the x-waiver requirement for certain physicians. Pursuant to the exemption, a physician licensed under state law who possessed a DEA registration could prescribe schedule III, IV, or V drugs, such as buprenorphine, without first obtaining an x-waiver. The x-waiver was still available, however, for those physicians who wished to obtain one.

This announcement came on the heels of legislative efforts to amend the statute to remove the DATA waiver requirement. In 2019, Senators Maggie Hassan (D-NH) and Lisa Murkowski (R-AK) introduced the bipartisan [Mainstreaming Addiction Treatment \(MAT\) Act](#) that would eliminate the need for this waiver, however, the legislation did not pass the Senate.

Trump Administration's Exemption Details

Practitioners Affected: The exemption covered **physicians** who are licensed under state law and possessed a DEA registration. Physicians using the exemption could only treat patients located in states where the physician was authorized to practice medicine.

Drugs Affected: The exemption applied to the drugs or formulations covered under the x-waiver of the Controlled Substances Act, such as buprenorphine, and not methadone.

Prescription: Physicians using the exemption were required to **place an "X" on the prescription** and clearly identify that the prescription was being written for opioid use disorders.

Limitation on Number of Patients

Physicians using this exemption were limited to treating **no more than 30 patients with buprenorphine for opioid use disorder at any one time** and had to maintain and retain records of the prescriptions issued. The 30-patient cap did not apply to hospital-based physicians, such as Emergency Department physicians, who initiated treatment in the Emergency Department but did not engage in a long term treatment relationship with the patient.

Will it Be Effective? *Not for now...*

The exemption would have become effective upon publication in the Federal Register but its effectiveness as an administrative agency action without statutory amendment or rulemaking was questioned by the Biden administration, who signaled the Guidance was "premature" and would not be effective at this time. The Guidance has, therefore, been effectively withdrawn for now.

SAMHSA (Substance Abuse and Mental Health Services Administration) recently posted the following notice:

Statement Regarding X-Waiver

On January 14, 2021, HHS announced forthcoming Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder. Unfortunately, the announcement was made prematurely. Therefore, the Guidelines previously announced cannot be issued at this time. However, HHS and ONDCP are committed to working with interagency partners to examine ways to increase access to buprenorphine, reduce overdose rates and save lives.

<https://www.samhsa.gov/sites/default/files/statement-regarding-xwaiver.pdf>

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