X-Waiver Changes Axed: Federal Government Backtracks on Previously Announced Rescission of Waiver Requirements

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Physicians, physician assistants, and advance practice nurses who have sought to treat opioid-addicted patients with Schedule III-V Controlled Substances that have been approved by the United States Food and Drug Administration for that indication have had to apply for a waiver under the Drug Addiction Treatment Act of 2000. Eligible medications are presently limited to buprenorphine-containing products such as Suboxone and Subutex.\[i\] The waiver is oftentimes referred to as the “X-Waiver,” and permits the practitioner to provide medication-assisted treatment (MAT) to patients suffering from opioid use disorder (OUD). The Substance Abuse and
Mental Health Services Administration (SAMHSA), a division of United States Department of Health and Human Services (HHS), defines MAT as “the use of medications, in combination with counseling and behavioral therapies, to provide a ‘whole-patient’ approach to the treatment of substance use disorders.”

In the waning days of the Trump administration, HHS announced a plan to expand practitioner ability to provide MAT to patients suffering from opioid use disorder. Citing the opioid epidemic’s toll on public health and the staggering recent amount of overdose deaths, HHS sought to modify the requirement that eligible practitioners must have the waiver before prescribing buprenorphine to patients with OUD. The elimination of or exemption from the X-Waiver requirement would have only applied to physicians, who would then be limited to treating no more than 30 patients at any one time.

The announcement, made on Jan. 14, 2021, six days before the inauguration of the Biden administration, left HHS little time to implement any meaningful changes. Although HHS published its notice in the Federal Register and indicated further guidance would be forthcoming, no such guidance was ever released. On Jan. 27, 2021, the Biden administration announced its cancellation of changes to the X-Waiver program. Declaring HHS’s announcement of the change as “premature,” the White House nevertheless pledged to increase practitioner access to buprenorphine.

The reversal notwithstanding, there are questions as to whether HHS could have legally made these changes to the X-Waiver program, even if the change was made in a timely and meaningful fashion. The X-Waiver requirement was created by an act of Congress, namely, Section 3502 of the Children’s Health Act of 2000 (Act). The HHS secretary’s authority to issue practical guidelines – like the one issued on Jan. 14, 2021 – is contained in § 823(g)(2)(H)(i)(II) of the same act. But while the secretary may issue practical guidelines to exempt certain requirements and regulations, the secretary’s ability override statutorily defined conditions on dispensing these narcotic drugs is suspect. A regulatory promulgation cannot override a statutory enactment.

Despite the reversal, broad support for the elimination of the X-Waiver requirement may see it revived in the future. United States Senators Maggie Hassan (D-N.H.) and Lisa Murkowski (R-Alaska) plan to introduce a bill to eliminate the X-Waiver requirement. However, as of right now, the X-Waiver is still required for the prescribing of buprenorphine-containing products for OUD.

Buprenorphine is a FDA-approved OUD treatment that acts as an opioid partial agonist by producing weaker euphoria and respiratory depression effects than full opioid agonists such as methadone and heroin. https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/buprenorphine.


This section modified the Controlled Substances Act at 21 U.S.C. § 823(g).

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