

# Biden administration boosts access to overdose prevention, treatment

JUN 2, 2021

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As the drug-overdose epidemic continues during the COVID-19 pandemic, the Biden administration has taken steps that will save lives and remove barriers to overdose prevention and treatment.

Recent statistics indicate that nearly 90,000 overdose deaths occurred in the U.S. between September 2019 and September 2020. Isolation and financial insecurity caused by COVID-19 has accounted for some of the increase in overdose fatalities, but the evolving epidemic is now being fueled largely by illicitly manufactured and adulterated fentanyl and fentanyl analogs.

To help combat this, the Food and Drug Administration (FDA) recently approved a new nasal spray that delivers 8 milligrams of naloxone. Previously approved products only delivered 2- or 4-milligram doses.

"The FDA recognized that the drug overdose epidemic is ever-changing, and government regulators must be agile to ensure that patients at risk of an opioid-related overdose have effective medication to help save their lives," said AMA Immediate Past President Patrice A. Harris, MD, MA, chair of the AMA Opioid Task Force since its inception in 2014.

"By approving a higher dose of naloxone hydrochloride nasal-spray product to treat opioid overdose, the FDA is making sure the overdose-reversing drug is potent enough to counteract the increasingly lethal and illicitly manufactured fentanyl and fentanyl analogs," Dr. Harris added. "Now, we must make sure that the new version of naloxone is placed on the lowest cost-sharing tier with low or no cost-sharing and also available in pharmacies."

The AMA also urges manufacturers of overdose reversal agents to submit applications to make the lifesaving medication available over the counter.

## HHS waives DEA buprenorphine X waiver

Health and Human Services (HHS) Secretary Xavier Becerra also issued new practice guidelines for the administration of buprenorphine for treating opioid-use disorder (OUD).

For physicians and other prescribers who intend to only treat 30 patients or fewer, the guidelines remove requirements, including that they complete an eight-hour training course to obtain a Drug Enforcement Administration (DEA) X waiver to prescribe buprenorphine.

To qualify for this exemption, physicians and other qualified health care professionals must have a state-issued license, valid DEA registration, and submit to the Substance Abuse and Mental Health Services Administration a notice of their intent to prescribe. The AMA strongly encourages physicians to take advantage of this new opportunity to care for patients with an opioid-use disorder.

The AMA has long advocated for these changes. A 2020 report by the AMA and Manatt Health further explains the barriers created by the X-waiver process.

Patients are struggling to find physicians who are authorized to prescribe buprenorphine, Dr. Harris noted, but onerous regulations have discouraged physicians from becoming certified to prescribe buprenorphine for OUD. These rules have increased the stigma against buprenorphine and had an inequitable impact.

“With this change, office-based physicians and physician-led teams working with patients to manage their other medical conditions can also treat them for their OUD without being subjected to separate, burdensome and stigmatizing requirements,” said Dr. Harris, a child psychiatrist in Atlanta. “Physicians should become educated about managing patients with OUD to help stem the nationwide overdose epidemic and ease the persistent health disparities facing our patients.”

The AMA supports legislation to remove the waiver requirements altogether—the bipartisan, bicameral Mainstreaming Addiction Treatment (MAT) Act of 2021. In its letter to the House and Senate sponsors, the AMA said the measure “would end an outdated and burdensome requirement in federal law that restricts physicians and other medical professionals from prescribing buprenorphine in-office.”