Narcan lands OTC approval: What it means for patients, doctors

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The recent approval of naloxone for over-the-counter (OTC) sale means that people may be able to walk into a store and easily buy a medication that can save lives.

But that won't happen unless the drug's manufacturer and retailers take critical steps to ensure the naloxone product (marketed as Narcan) that was approved by the Food and Drug Administration (FDA) is widely available at an affordable price.

The manufacturer has announced it will price Narcan, a hydrochloride nasal spray that reverses opioid overdose, at about $50. More than 100,000 people die of drug overdoses in the U.S. each year, according to the Centers for Disease Control and Prevention.

That price point is “something that's going to be prohibitive for a lot of people,” said Bobby Mukkamala, MD, chair of the AMA Substance Use and Pain Care Task Force. “We strongly encourage that the price of this medication when it becomes over the counter become something that's affordable. It's inexcusable for manufacturers, honestly, to price their products to maximize profits over saving these 100,000-plus lives.”

Meanwhile, pharmacies and other retailers must stock the medication and overcome the stigma of engaging with customers who have used illicit drugs, Dr. Mukkamala said during an episode of “AMA Update” in which he discussed what the FDA's recent approval of OTC naloxone means for doctors and patients.

OTC approval a long time coming

The move to make naloxone available over the counter is “something the AMA has championed for a long time,” Dr. Mukkamala said.
“If it weren't for naloxone, there'd be tens of thousands of more Americans dying from opioid overdose. And this is related to illicitly manufactured fentanyl, which has really driven this increase in deaths, a record number of deaths this past year,” he said.

The AMA urges chain pharmacies, vending machines, supermarkets, convenience stores, even gas stations to step up to sell OTC naloxone this summer.

“And more lives will be saved if naloxone is more widely available,” said Dr. Mukkamala.

**Reviving patients “in 2-3 minutes”**

The FDA approved naloxone for OTC status because it’s safe and easy to administer, said Dr. Mukkamala, an otolaryngologist in Flint, Michigan. Anyone who comes across a person who’s slumped over and shows signs of possible overdose—meaning they are unresponsive and have slow, shallow breathing—can unwrap this palm-sized device from a package and insert the tip of it into somebody’s nose and depress the plunger.

The medication usually revives someone within two or three minutes. “So it's very safe and effective. And with increased fentanyl access in our drug supply, it's going to save lives,” added Dr. Mukkamala, immediate past chair of the AMA Board of Trustees.

Regardless of whether it’s fentanyl, or drugs mixed with fentanyl such as cocaine or the animal tranquilizer xylazine, there’s no downside to giving naloxone when an overdose is suspected, he continued.

“Chances are there will be some opioid, and this is going to reverse at least that component,” Dr. Mukkamala said.

The AMA believes that science, evidence, and compassion must continue to guide patient care and policy change as the nation’s opioid epidemic evolves into a more dangerous and complicated illicit drug overdose epidemic. Learn more at the AMA’s End the Epidemic website.

**Timely administration key to saving lives**

Physicians need to be willing to talk to their patients about the risk of overdose, said Dr. Mukkamala. After surgery, he always looks at the opioid and medication history of a patient before writing a prescription—and engages those patients in conversation if he thinks there’s a concern.
With naloxone, timely administration can save lives, he emphasized. Patients should know how to get naloxone and how to safely administer it. Watch this AMA video learn how to administer naloxone.

In separate news, a comprehensive resource has been created on the AMA Ed Hub™ to help physicians and other health professionals complete the new, one-time eight-hour training requirement issued by the Drug Enforcement Administration (DEA) on treating and managing patients with opioid or other substance-use disorders.

The listed CME activities can be taken in any combination to fulfill the eight-hour requirement that applies to DEA-registered physicians.

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