

## FDA approval of Narcan as over-the-counter drug will boost accessibility, save lives, health officials say

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As soon as this summer, people will be able to purchase the opioid overdose reversal medication Narcan as easily as they can buy Tylenol



and Benadryl, after the U.S. Food and Drug Administration approved it last week to be sold over the counter.

Doctors and substance use recovery advocates cheered the decision, which they say will make <u>naloxone</u>—the medication's generic name—more accessible, including in places like Baltimore, where residents have been able to buy it at pharmacies without a prescription since 2015.

"Bottom line, I think it's going to save lives," said Dr. Gentry Wilkerson, an emergency medicine physician at the University of Maryland Medical Center and co-lead of the downtown Baltimore hospital's Opioid Safety Council.

Drug overdoses remain a serious public health problem nationwide. In the 12-month period preceding October 2022, more than 101,750 people died from an overdose, with many caused by synthetic opioids like fentanyl, according to a statement from the FDA.

In the year preceding November 2022, 958 people in Baltimore died from an overdose, a slight decrease from the previous year, when 1,066 died, according to the Maryland Overdose Data Dashboard.

The Narcan <u>nasal spray</u> is the most dispensed brand of the medication, according to the company's website, and is the first naloxone product to be approved for over-the-counter sale. The spray comes in a package of two 4-milligram doses, though the drug's manufacturer, Gaithersburgbased Emergent BioSolutions, says most overdoses can be reversed with a single dose.

While Baltimore was one of the first jurisdictions in the country to issue a standing order for naloxone—extending a blanket prescription for all city residents—every state and Washington, D.C., now have laws



allowing people to access the drug. Naloxone also is distributed for free by hospitals, <u>community organizations</u> and health departments nationwide.

Access to naloxone at pharmacies is growing—naloxone prescriptions dispensed from pharmacies increased from about 134,000 in 2016 to nearly 1.2 million in 2021, according to data from the American Medical Association—but not every pharmacy carries the drug.

The FDA's decision Wednesday paves the way for Narcan to be sold directly to people in places like drugstores, convenience stores, grocery stores and gas stations, as well as online, according to the statement from the federal agency.

Along with making the drug more available, Wilkerson said, the decision also could reduce the stigma associated with buying naloxone and make more people willing to have it in their homes.

"They're the ones that may have old opioid prescriptions in their medicine cabinet that a toddler gets into or somebody visiting their house takes," he said. "It's better to have naloxone on hand than waiting for an ambulance to come."

But, he added, "it's not all rainbows and unicorns."

Emergent BioSolutions has yet to say how much Narcan will cost. Once it becomes available over the counter, Wilkerson said, insurance companies may not cover it.

At the University of Maryland Medical Center's pharmacy as of Wednesday, it would cost a little under \$30 to purchase Narcan out-of-pocket, Wilkerson said. While that may be cheaper than other pharmacies, where two doses of Narcan can go for around \$50, for some



people, the doctor said, \$30 is still a lot of money.

But Wilkerson doesn't foresee the <u>medical center</u> discontinuing its free Narcan distribution program following the FDA decision. The University of Maryland Medical System is putting together an application to receive naloxone and fentanyl test strips from the Maryland Department of Health, which the system's 11 hospitals will then be able to distribute to patients at no cost, Wilkerson said.

The Baltimore City Health Department and Baltimore County Department of Health also plan to continue their naloxone training and distribution programs.

Last year, Baltimore County's health department trained 1,180 people to administer naloxone in a variety of settings, including the county detention center, the health department's substance use treatment center and virtual training sessions, offered multiple times a month.

"On our end, things are not going to change," said Amy Park, division chief of the county health department's Local Addictions Authority.

"We're going to make sure that people have access."

Although people won't be required to be trained in how to use Narcan before purchasing it over the counter, it will still be important to educate people in overdose prevention, said Jennifer Martin, deputy commissioner for the Baltimore City Health Department's Division of Population Health and Disease Prevention. Doing so helps people feel comfortable approaching someone who appears to be overdosing, she said.

"Having [Narcan] is wonderful, but if you're not comfortable using it, then it doesn't matter if you have it," she said.



Martin and Park reflected on how the conversation has changed over time regarding Narcan distribution programs. Initially, people worried giving naloxone to community members—especially those actively struggling with <u>substance use disorder</u>—would encourage them to engage in riskier behavior, and use in higher doses without fear of overdose.

But harm reduction programs are now far more accepted—in the medical community, as well as the general public.

"We've been going through this opioid epidemic for quite some time now. It's not new. And people know that it has just gotten worse over the last few years, despite everybody's effort," Wilkerson said. "I think, culturally, people are ready for this to be over and to try what needs to be done."

Wilkerson has two naloxone kits at his house, and he keeps some in his office, his car and his backpack. As an emergency room doctor, he's administered the medication to patients many times.

But the one time he needed naloxone outside a medical setting, he didn't have it. Instead, the only way he could keep the patient breathing was by vigorously rubbing his sternum. By the time paramedics arrived with the medication, Wilkerson had no skin left on his knuckle.

Within 45 seconds of the patient receiving naloxone, he got up and walked away. It's amazing how effective the medication is, Wilkerson said.

"It's the closest thing we have to a miracle."

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