
Detroit Free Press

Detroit Free Press: FDA approves Narcan for over-the-counter sale: What to know

[Georgea Kovanis](#) March 29, 2023

In an effort to stem the nation's deadly opioid epidemic, the U.S. Food and Drug Administration on Wednesday approved the opioid overdose reversing drug Narcan for over-the-counter sales. In Michigan, a standing order enacted in 2017, made Narcan (generic: naloxone) available without a prescription; it is already for sale at participating pharmacies to anyone who asks for it. It is also distributed free of charge by community organizations and health departments.

But Wednesday's change paves the way for Narcan to be sold in places other than pharmacies, including party stores, gas stations and grocery stores, increasing access to the lifesaving drug. And it means Narcan would move from a medication shoppers need to ask a pharmacist for — because until Wednesday it was still classified as a prescription medication, it was kept behind the pharmacy counter — to one that could be placed on self-serve shelves along with aspirin and antacids. Experts say the change in placement of Narcan could reduce the stigma in having to ask a pharmacist to retrieve it. The manufacturer, Emergent BioSolutions, said it expects to have over-the-counter Narcan available to retailers by the end of the summer. It said current stock would not be eligible to move to self-service shelves; drugs for over-the-counter sales need to be labeled as such.

It is also unclear how this change will impact the price of Narcan. The FDA said pricing will be determined by the manufacturer. Currently, a Narcan kit — which contains two 4 mg doses of nasal spray — can cost up to \$143, though it is covered by some insurances and coupons are available to offset the cost. Still, for those without insurance, it can be cost prohibitive.

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“The FDA remains committed to addressing the evolving complexities of the overdose crisis. As part of this work, the agency has used its regulatory authority to facilitate greater access to naloxone by encouraging the development of and approving an over-the-counter naloxone product to address the dire public health need,” FDA Commissioner Dr. Robert M. Califf said in a statement. “Today’s approval of OTC naloxone nasal spray will help improve access to naloxone, increase the number of locations where it’s available and help reduce opioid overdose deaths throughout the country. We encourage the manufacturer to make accessibility to the product a priority by making it available as soon as possible and at an affordable price.”

During the 12-month period ending in October 2022, 101,751 people across the nation — including 2,889 in Michigan — died from drug overdoses, according to preliminary data from the U.S. Centers for Disease Control and Prevention. The majority of those overdose deaths are tied to fentanyl, the ultra-potent synthetic opioid that has infiltrated the street drug supply.

The over-the-counter status applies only to 4 mg doses of Narcan nasal spray; other forms of Narcan will not be sold over the counter.

The big question surrounding the FDA's action is whether stores will actually stock Narcan. Only 59% of the pharmacies in Michigan participate in the standing order, which allows Narcan to be sold without a prescription.