

# **OTC Naloxone Guidance** for Pharmacists

### What changed?

Previously, naloxone, an opioid overdose reversal medications (OORM). was only available through a prescription from a qualified healthcare provider, including from pharmacists in Oregon. In 2023, the U.S. Food and Drug Administration (FDA) approved the first over the counter (OTC) naloxone products.



#### What are Opioid Overdose Reversal Medications?

OORMs are lifesaving short-acting opioid overdose reversal medications approved by the FDA to reverse an opioid overdose. The two FDA-approved OORMs are naloxone and nalmefene. Naloxone, or brand name Narcan, is the most common. The FDA's approval of OTC naloxone nasal spray now allows individuals to access this medication without a prescription.

### **Regulatory Changes**

- Naloxone sold OTC must have FDA-approved labeling that includes clear instructions on use, storage, and safety information.
- Pharmacists are no longer required to document the sale of OTC naloxone as a prescription medication unless the OTC form is dispensed under the protocol.

#### **OTC Forms Available:**

- Narcan® naloxone nasal spray, 4ma
- Padagis® naloxone nasal Spray, 4mg (generic)
- RiVive™ naloxone nasal spray, 3ma



# Common barriers



## **Pharmacy Solutions**

- X Pharmacy only has Rx naloxone
- Stock OTC naloxone: Ensure your pharmacy has an adequate supply of both prescription and OTC naloxone.
- X OTC naloxone is placed behind the counter
- Ensure easy access to naloxone: Pharmacies should have ways that patients can access naloxone easily and anonymously.
- X OTC naloxone can be costly (up to \$50)
- ✓ Reduce cost burdens for patients: Pharmacy staff should inform patients that some insurances or health savings accounts may cover the full cost. Consider still prescribing naloxone, when covered by insurance or providing community-based resources to obtain free naloxone.
- X Lack of patient education
- Offer patient counseling: While counseling is not required for OTC naloxone, unless the OTC form is dispensed under the protocol, pharmacists should continue to offer patients education on overdose response, proper administration, and the importance of calling 911.



TAKE-AWAY: OTC naloxone increases access for Oregonians and can help save lives.