



Increasing Naloxone Access in Kentucky: Implementation of SB192 by Pharmacists

October 2021 Update

Updates to 201 KAR 2:360

Amendments to 201 KAR 2:360 went into effect on October 21, 2021. The following changes simplify protocol dispensing for Kentucky pharmacists:

- **Certification:** Pharmacists are no longer required to submit proof of education and training to the Board of Pharmacy in order to become naloxone certified. Pharmacists must still complete the application and be issued a license that includes "Naloxone Certified."
- **Mandatory Education:** Pharmacists who dispense naloxone under a protocol are required to provide verbal counseling and written education appropriate to the dosage form of naloxone dispensed. However, 201 KAR 2:360 no longer lists specific educational elements that must be included in the provided education.
- **Harm Reduction Programs:** Pharmacists may dispense naloxone to a person or agency operating a harm-reduction program that provides training on the administration of naloxone to the public, regardless of who the ultimate user of the naloxone may be.

New Naloxone Products Approved By FDA

In addition to Narcan Nasal Spray, the following products have been approved by the FDA for the emergency treatment of known or suspected opioid overdose:

- **Kloxxado:** Intranasal naloxone hydrochloride 8 mg/0.1 mL, approved April 30, 2021. Each carton contains two single-use nasal sprays (NDC: 59467-0679-01).
- **Zimhi:** Intramuscular or subcutaneous naloxone hydrochloride 5 mg/0.5 mL, approved October 18, 2021. Product is available in a case containing one single-use pre-filled syringe (NDC: 38739-0600-01) or as a two-pack of single-use pre-filled syringes, each in their own case (NDC: 38739-0600-02).

Reminder: Review and Update Protocols Regularly

Pharmacists who initiate the dispensing of naloxone under a protocol must follow the terms of the protocol, even if they are more strict than current regulations allow. For example, a protocol may limit dispensing to a specific NDC or contain specific counseling points the pharmacist must review with patients.