



INTENT TO DRAFT REGULATIONS, AND INTERIM GUIDANCE PERTAINING TO SB 23 / NALOXONE DISPENSATION

This interim guidance is adopted by the Alaska Board of Pharmacy to guide licensees until regulations governing the dispensation of opioid overdose drugs are implemented. While this guidance is not law, it is more than a recommendation. In other words, this guidance is an official opinion of the Alaska Board of Pharmacy regarding the practice of pharmacy as it relates to dispensing opioid drugs under SB 23. Facility policies may restrict practice further in their setting and/or require additional expectations related to competency, validation, training, and supervision to assure safety of their client population and/or decrease risk. The Alaska Board of Pharmacy publishes this guidance in accordance with AS 08.80.030(b).

Intent to draft regulations:

I. Requirement to establish standards: The Alaska State Legislature adopted SB 23, effective 3/15/16, relating to the practice of pharmacy; relating to the dispensing of opioid overdose drugs by a pharmacist; relating to opioid overdose drugs and to immunity for prescribing, providing, or administering opioid overdose drugs; and providing for an effective date. SB 23 requires the Board of Pharmacy (board) to establish standards for the independent dispensing by a pharmacist of an opioid overdose drug under AS 17.20.085, and the dispensing pharmacist to complete an approved opioid overdose training program.

II. Intent to establish standards: It is the board's intent to establish standards for the independent dispensing by a pharmacist of an opioid overdose drug, including the completion of an opioid overdose training program approved by the board. The board intends to establish these standards in regulations.

III. Notice of regulations: When regulations are drafted and proposed, they will be noticed in accordance with the Alaska Administrative Procedure Act and available on the board's web site at <https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx>.

Interim guidance:

- I. Definition:** "Recipient" means the person to whom naloxone hydrochloride is furnished.
- II. Training:** In accordance with 12 AAC 52.340, any pharmacist dispensing an FDA approved opioid overdose product must complete a single training session which consists of 1 hour of continuing education specific to the use of naloxone hydrochloride in all routes of administration of FDA

approved product forms.

III. Protocol for Pharmacists Furnishing Naloxone Hydrochloride:

Dispensation: Before dispensing the naloxone hydrochloride to the recipient, the pharmacist shall:

- 1) screen the potential recipient for any contraindications; and
- 2) provide the recipient information about opioid overdose prevention, recognition, and response of the antidote naloxone.

When dispensing naloxone hydrochloride products, the pharmacist may:

- 1) provide the recipient with appropriate counseling and information on the product furnished, including dosing, administration, effectiveness, adverse effects, storage conditions, shelf-life, and safety in accordance with 12 AAC 52.585; and
- 2) offer the recipient any informational resources on hand and referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

Product Selection: A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector, or in another FDA approved product form. A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

Labeling: A pharmacist shall label the naloxone hydrochloride in accordance with 12 AAC 52.480. The directions on the label must state how to use the corresponding product, including the direction to contact 911 or other available emergency services. "Use as directed" cannot be used as the sole direction on the label.

Fact Sheet: The pharmacist shall provide the recipient a copy of a naloxone fact sheet.

Documentation: In accordance with 12 AAC 52.450, each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient and securely stored within the originating pharmacy or health care facility for a period of two years from the date of dispense.