

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 40 AUTHORIZATION, TRAINING AND PROCEDURES FOR PRESCRIBING AND DISPENSING NALOXONE HYDROCHLORIDE

Summary: This chapter establishes procedures and standards for authorizing pharmacists to prescribe and dispense naloxone hydrochloride (“Naloxone HCl”) and training requirements and protocols for prescribing and dispensing naloxone hydrochloride.

1. Purpose.

These rules establish the procedures and standards by which a pharmacist may dispense naloxone hydrochloride under a prescription order, standing drug order, or collaborative drug therapy management agreement and may prescribe naloxone hydrochloride to a person 21 years of age or older without there being a prescription drug order, standing drug order, or collaborative drug therapy management agreement.

2. Definitions

1. **Caregiver.** “Caregiver” means a family member, friend, or individual in a position to have recurring contact with a person at risk of experiencing an opioid-related overdose.
2. **Emergency opioid antagonist.** “Emergency opioid antagonist” means Naloxone HCl or a similarly acting drug that blocks the effects of opioids administered from outside the body and that is approved by the United States Food and Drug Administration for the treatment of an opioid overdose.
3. **First responder.** “First responder” means any individual or agency that provides emergency on-site care to a person until the arrival of a duly licensed ambulance service. This shall include, but is not limited to, individuals who routinely respond to calls for assistance through an affiliation with law enforcement agencies, fire departments and rescue agencies.
4. **Opioid Antagonist.** “Opioid Antagonist” means Naloxone HCl or other similarly acting drug that is approved by the federal Food and Drug Administration for the treatment of an opioid overdose.
5. **Patient at risk.** “Patient at risk” means a person at risk of experiencing an opioid-related overdose.

3. Authorization to Prescribe and Dispense Naloxone Hydrochloride

1. A pharmacist may not dispense Naloxone HCl without a prescription drug order, standing order, or collaborative drug therapy management agreement unless authorized to prescribe Naloxone HCl in accordance with this Chapter.

2. All licensed pharmacists are already authorized and trained to dispense prescription medications, including naloxone hydrochloride, by prescription drug order, standing order, or under a collaborative drug therapy management agreement and, as such, additional Board authorization to dispense naloxone hydrochloride is not required. However, a licensed pharmacist shall, prior to dispensing naloxone hydrochloride, obtain 2 hours of training on safe dispensing of an opioid antagonist, counseling, providing instructions to the person receiving the opioid antagonist, and its use as rescue therapy for an opioid overdose as described in Section 4 and shall comply with requirements described in Sections 7, 8, 10 and 11. The pharmacist shall retain a record of training and present it to the Board upon request or if subject to a continuing education audit.
3. To become authorized to prescribe Naloxone HCl, a pharmacist must submit to the Board an application on a form prescribed by the Board and comply with the following requirements. There is no cost for the initial application and license.

The pharmacist must:

- A. Hold a valid Maine pharmacist license that is not subject to any conditions of licensure affecting the scope of practice; and
- B. Attest in a manner required by the Board to having completed training as described in Section 4 of this chapter and such other information as the Board may require.

Incomplete applications will not be considered and will be returned to the applicant. Board authorization is subject to renewal annually at no cost.

4. Training Requirement for Pharmacist Authorization to Prescribe

A pharmacist who applies for authorization to initiate a prescription drug order for an opioid antagonist shall obtain 2 hours of educational training that is approved by the Accreditation Council for Pharmacy Education (“ACPE”) related to writing prescription drug orders, the safe dispensing of an opioid antagonist, counseling and providing instructions to the person receiving the opioid antagonist, and its use as rescue therapy for an opioid overdose, which addresses all of the following topics:

1. Risk factors for opioid abuse and overdose;
2. Opioid overdose prevention;
3. Recognizing and responding to opioid overdoses;
4. Indications for use of Naloxone HCl as rescue therapy;
5. Contraindications for use of an opioid antagonist;
6. Proper storage and expiration of an opioid antagonist product dispensed;
7. Procedures for administration of an opioid antagonist;
8. Adverse effects associated with an opioid antagonist rescue therapy;
9. Identification of a patient who meets the criteria for provision of an opioid antagonist;
10. Required education to provide to persons receiving an opioid antagonist;

11. Required elements of protocol to initiate dispensing of an opioid antagonist;
12. Required documentation when initiating dispensing of an opioid antagonist; and
13. Actions and interventions to be used upon the occurrence of a clinical event.

5. Eligible Recipients

Persons eligible to receive Naloxone HCl under this protocol include:

1. Patients at risk;
2. Individuals who are members of a patient at risk's immediate family or a friend of the person or to another person in a position to assist the person if the person is at risk of experiencing an opioid-related drug overdose;
3. Persons with history of receiving emergency medical care for acute opioid poisoning or overdose;
4. Persons with a suspected or confirmed history of substance abuse, dependence or non-medical use of prescription or illegal drugs;
5. Persons receiving high-dose opioid prescriptions (E.g. >100 mg morphine equivalent);
6. Persons who are opioid naïve and receiving a first prescription for methadone for pain;
7. Persons starting buprenorphine or methadone for addiction treatment;
8. Persons on opioid prescriptions in combination with:
 - A. Smoking, COPD, emphysema, sleep apnea, or other respiratory illness;
 - B. Renal dysfunction, hepatic disease, or cardiac disease;
 - C. Known or suspected alcohol use;
 - D. Anyone who injects opioids, such as heroin or fentanyl;
 - E. Concurrent benzodiazepine or other sedative prescription; or
 - F. Concurrent antidepressant prescription;
9. Persons who may have difficulty accessing emergency medical services.

6. Prescribe and Dispense

A Board-authorized pharmacist may prescribe an oral, injectable, intranasal or any other form of opiate antagonist and the necessary medical supplies to administer the naloxone hydrochloride to a person that the pharmacist reasonably determines meets the eligible recipient criteria above in order to treat potential opioid overdoses. A pharmacist may write a prescription to meet the need on hand within the pharmacist's current workplace and not for purposes of providing a prescription to a patient at risk or caregiver to take away and present to another pharmacy for filling.

7. Documentation

Pharmacists must document in the pharmacy management system each person who receives a Naloxone HCl prescription under this chapter, which documentation shall include:

1. Name of the patient at risk, if known, or the name of the person requesting the Naloxone HCl prescription;
2. Name of the person to whom the prescription was dispensed.;
3. Name of the product;
4. Dose and route of administration and required delivery service;
5. Date dispensed;
6. Name of the prescribing pharmacist or practitioner; and
7. Name of the dispensing pharmacist who reviewed and provided the patient or caregiver receiving an opioid antagonist, educational materials appropriate to the dosage form of the opioid antagonist dispensed as described in Section 10(2) of this chapter.

8. Notice to the person's physician

Within 7 days of prescribing or dispensing Naloxone HCl, the pharmacist shall provide to the physician of the patient at risk, written notification via fax or other appropriate designated method that Naloxone HCl was provided to the physician's patient under this protocol. The notification shall include the person's name, the opioid antagonist prescribed or dispensed by the pharmacist and date dispensed. If the physician is unknown, it shall be so noted in the pharmacy management system.

9. Prescribing Opioid Antagonist Emergency Rescue Kits

A Board-authorized pharmacist may prescribe Naloxone HCl emergency rescue kits or upon a standing order or collaborative drug therapy management agreement. The kit must be labeled and include the expiration date. Prepared patient information must be provided with the kit and the pharmacist must have a complete understanding of the information distributed to the person, caregiver or first responder. A record of prescribing and dispensing rescue kits must be maintained.

10. Counseling/Instructions to the Person Being Dispensed an Opioid Antagonist

A pharmacist must provide counseling, which may not be refused or declined, to the persons being dispensed an opioid antagonist. At the time of dispensing an opioid antagonist, the pharmacist shall provide written instructions on the proper response to an opioid-related overdose, including instructions for seeking immediate medical attention. Counseling shall, at a minimum, include the following:

1. Instruct the person to whom an opioid antagonist is dispensed to summon emergency services as soon as practicable either before or after administering an opioid antagonist.
2. Personally provide the service of oral counseling and written education materials to the person to whom an opioid antagonist is dispensed, appropriate to the dosage form of the an opioid antagonist dispensed, including, but not limited to, all of the following:

- A. Risk factors of opioid overdose;
- B. Strategies to prevent opioid overdose;
- C. Signs of opioid overdose;
- D. Steps in responding to an overdose;
- E. Information on Naloxone HCl;
- F. Procedures for administering Naloxone HCl;
- G. Proper storage and expiration of Naloxone HCl product dispensed; and
- H. Information on where to obtain a referral for substance abuse treatment.

The pharmacist dispensing an opioid antagonist shall ensure that all pharmacy interns under their oversight who dispense an opioid antagonist pursuant to this rule are appropriately trained on the use of an opioid antagonist and can meet the counseling requirements.

11. Pharmacist Intern

A pharmacy intern may under the direct supervision and direction of a pharmacist dispense an opioid antagonist. For purposes of this chapter, direct supervision means that a pharmacist is physically present within the same work area as the pharmacy intern to oversee and direct the dispensing activity.

[Note: Pursuant to 32 MRS §13702-A, Section 24-A (B) describes a pharmacy intern as a person who, “Is licensed with the board and is authorized to engage in the practice of pharmacy while under the direct supervision of a licensed pharmacist.”]

Statutory Authority: 32 MRS §§13720 and 13815

Effective Date: