



STATE OF
OHIO
BOARD OF PHARMACY

Naloxone for Emergency Use and Distribution Via Automated Mechanism

Updated 3/30/2021

[Section 4729.515](#) of the Ohio Revised Code authorizes a terminal distributor of dangerous drugs (TDDD) to acquire a supply of naloxone, and to maintain the supply at an alternative location, to use in emergency situations or to distribute through an automated mechanism.

To implement this law, the Board adopted rule [4729:5-3-19](#) of the Administrative Code.

To assist licensees in complying with Ohio law, the State of Ohio Board of Pharmacy has developed the following frequently asked questions. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting:

<http://www.pharmacy.ohio.gov/contact.aspx>.

The frequently asked questions are broken down into two parts, starting on the next page:

- I. [Frequently Asked Questions – Naloxone for Emergency Use](#)
- II. [Frequently Asked Questions – Distribution of Naloxone via Automated Mechanism](#)



Frequently Asked Questions – Naloxone for Emergency Use

Naloxone for emergency use is the off-site storage of naloxone by a licensed terminal distributor of dangerous drugs for use in an emergency (i.e., responding to an overdose). This guidance does not apply to service entities that maintain naloxone for emergency use to respond to an overdose that occurs on the premise of the service entity. Rather, it is for naloxone that is maintained off-site for emergency purposes (similar to the use of automated external defibrillators).

For more information about service entities, visit: www.pharmacy.ohio.gov/Service

Q1) I would like to maintain naloxone for emergency use, am I required to obtain a TDDD license?

Yes. While the law exempts service entities that maintain naloxone for personally furnishing and for emergency administration by staff and volunteers, it still requires any entity maintaining naloxone at an off-site location (i.e., not maintained on the premises of the service entity) for emergency use to obtain a TDDD license.

Q2) How do I obtain a TDDD license?

To obtain a TDDD license, your organization will require an [eLicense](#) Ohio account. To assist applicants, the Board created a step-by-step guide for registering for an eLicense account. The guide can be accessed [here](#).

After creating an account, use this guide to [add a new license](#). An applicant should select the following license type: *Terminal – Facility – Category II – First Aid Department*.

Q3) Am I required to provide educational materials for individuals accessing emergency naloxone?

Yes. Ohio law and [Board rules](#) require a licensee to provide instructions regarding the emergency administration of naloxone to any individual who accesses the naloxone, to include:

1. Specific instruction to summon emergency services pursuant to division (D)(2) of section 4729.515 of the Revised Code.
2. Procedures for administering naloxone contained within the kit, including the possible administration of multiple doses.
3. Performing rescue breathing and the use of a face shield or other rescue breathing barrier device, which shall be provided with the naloxone.
4. Proper method for placing an individual into the recovery position.

Instructions may include a poster or signage providing this information or may be a handout or other written documentation that accompanies the naloxone.

Q4) Am I required to develop a process for determining when the emergency naloxone has been accessed?

Ohio law and [Board rules](#) requires the establishment of a process to notify the terminal distributor that the naloxone has been accessed within a reasonable time of it being accessed. Board policy and pending rules require the use of one of the following processes:

1. Documented checks of the emergency naloxone and its required components, to be conducted at least every thirty days, by an employee of the terminal distributor of dangerous drugs. The terminal distributor shall include a telephone number where persons can report that the emergency naloxone has been used and needs replenishment.
2. An automated alert that notifies the terminal distributor when the emergency naloxone is accessed.
3. Any other method approved by the Board's Executive Director or the Director's designee. Licensee's requesting another notification process, should submit a detailed proposal to contact@pharmacy.ohio.gov.

IMPORTANT: Except in instances where naloxone is not commercially available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler, a terminal distributor of dangerous drugs must replace any naloxone and, if missing or used, any required components (instructions, rescue breathing barrier device, etc.) no later than forty-eight hours following notification (using one of the methods listed above) that naloxone has been accessed.

Q5) What are the storage requirements for maintaining naloxone for emergency use?

Ohio law and [Board rules](#) require naloxone for emergency use to be maintained in accordance with the manufacturer's or distributor's instructions, including proper temperature storage. As such, a TDDD must comply with all the following:

1. All naloxone maintained for emergency use in shall be sealed in a tamper-evident manner to ensure the integrity of the drug. **NOTE:** The Board defines "tamper-evident" as a package, storage container or other physical barrier that is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.
2. Any naloxone that shows sign of tampering or adulteration shall be immediately removed by the terminal distributor of dangerous drugs and replaced within forty-eight hours of discovering the naloxone has been tampered with or is adulterated.
3. A terminal distributor shall develop and implement a policy to ensure that naloxone that exceeds its manufacturer's expiration date is removed and properly disposed.

Q6) Are there any record keeping requirements for naloxone maintained for emergency use?

A terminal distributor maintaining naloxone for emergency use must maintain the following records:

1. Maintain a complete list that includes the address and description of the location (e.g. first floor hallway, second floor conference room, etc.) of where the terminal distributor maintains the naloxone for emergency use. The list shall be immediately available for inspection upon request of an employee of the board.
2. Maintain a record of the naloxone stored emergency use that includes the name of the drug, strength, dosage form, national drug code, and expiration date. Records shall be readily retrievable (be produced within three business days) and maintained for a period of three years.

Q7) Are there any other requirements for naloxone for emergency use?

Licensees must ensure the naloxone is maintained in a container or device that is securely fastened to a permanent structure and is clearly marked to indicate naloxone is available for emergency use.

Q8) Do I need a prescriber protocol or prescription to access and use the emergency naloxone?

No. Section [4729.515](#) of the Revised Code does not require a prescriber protocol or prescription to access and use the emergency naloxone.

Q9) Does the law offer liability protections for entities providing naloxone for emergency use?

Division (E) of section [4729.515](#) of the Revised Code states:

(E) An individual is not liable for or subject to any of the following for injury, death, or loss to person or property that allegedly arises from an act or omission associated with any action authorized by this section, unless the act or omission constitutes willful or wanton misconduct: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

Q10) Does the Board have a sample inspection guide for licensee's providing naloxone for emergency use?

Yes. The Board incorporated a standard set of inspection questions on this topic in the following TDDD inspection guides (see section entitled ***Naloxone for Emergency Use***):

- [Outpatient Pharmacies](#) – 4729:5-5
- [Pain Management Clinics](#) – 4729:5-11

- [First Aid Departments](#) – 4729:5-13
- [Office-Based Opioid Treatment Facilities](#) – 4729:5-18
- [Clinic and Prescriber Offices](#) – 4729:5-19
- [Opioid Treatment Programs](#) – 4729:5-21
- [Non-limited Facilities](#) – 4729:5-22
- [Limited Facilities](#) – 4729:5-23

Frequently Asked Questions – Distribution of Naloxone via Automated Mechanism

Automated mechanisms for naloxone distribution do not require a protocol or prescription to distribute naloxone. This guidance applies to all automated mechanisms used to distribute naloxone per OAC [4729:5-3-19](#).

Q1) I would like to maintain an automated dispensing machine for naloxone, am I required to obtain a TDDD license?

Yes. While the law exempts service entities that maintain naloxone for personally furnishing and for emergency administration by staff and volunteers, it still requires any entity distributing naloxone via an automated mechanism to obtain a TDDD license.

Q2) How do I obtain a TDDD license?

To obtain a TDDD license, your organization will require an [eLicense](#) Ohio account. To assist applicants, the Board created a step-by-step guide for registering for an eLicense account. The guide can be accessed [here](#).

After creating an account, use this guide to [add a new license](#). An applicant should select the following license type: *Terminal – Facility – Category II – First Aid Department*.

Q3) Do I need a prescriber protocol or prescription to distribute naloxone via an automated mechanism?

No. Section [4729.515](#) of the Ohio Revised Code does not require a prescriber protocol or prescription to distribute via an automated mechanism.

Q4) What are the security requirements for the automated mechanisms?

The terminal distributor of dangerous drugs is required to ensure the mechanism is securely fastened to a permanent structure or is of an appropriate size and weight to reasonably prevent it from being removed from its intended location.

Q5) Am I required to develop a process for determining when to replenish the supply of naloxone maintained in the automated mechanism?

[Board rules](#) require the use of one of the following processes:

1. Documented checks of the mechanism, to be conducted at least every thirty days, by an employee of the terminal distributor of dangerous drugs.
2. An electronic system to monitor the inventory of naloxone within the mechanism.

3. Any other method approved by the Board's Executive Director or the Director's designee. Licensee's requesting another notification process, should submit a detailed proposal to contact@pharmacy.ohio.gov.

Q6) Am I required to provide educational materials for individuals accessing naloxone via an automated mechanism?

[Board rules](#) require a licensee to provide written educational materials to the person accessing the naloxone appropriate to the dosage form of naloxone distributed, including, but not limited to, all of the following:

1. Risk factors of opioid overdose.
2. Strategies to prevent opioid overdose.
3. Signs of opioid overdose.
4. Steps in responding to an overdose, including:
 - i. The proper method for placing an individual into the recovery position.
 - ii. Specific instruction to summon emergency services pursuant to division (D)(2) of section 4729.515 of the Revised Code.
5. Information on naloxone.
6. Procedures for administering naloxone.
7. Proper storage and expiration of naloxone product distributed.
8. Information on where to obtain a referral for substance abuse treatment.
9. Information on where individuals may call for additional questions regarding naloxone administration. The telephone number must include the hours where an appropriately trained representative is available to answer questions.

Q7) What are the storage requirements for maintaining naloxone in an automated mechanism?

Ohio law and [Board rules](#) require naloxone to be maintained in accordance with the manufacturer's or distributor's instructions, including proper temperature storage. . As such, a TDDD must comply with all the following:

1. Any naloxone that shows sign of tampering or adulteration shall be immediately removed by the terminal distributor of dangerous drugs.
2. A terminal distributor shall develop and implement a policy to ensure that naloxone that exceeds its manufacturer's expiration date is removed and properly disposed.

Q8) Are there any record keeping requirements for naloxone distributed via automated mechanism?

A terminal distributor must maintain the following records:

1. Maintain a complete list that includes the address and description of the location (e.g. first floor hallway, second floor conference room, etc.) of where the terminal distributor maintains an automated mechanism. The list shall be immediately available for inspection upon request of an employee of the board.
2. Maintain a record of the naloxone stored within the automated mechanism that includes the name, strength, dosage form, national drug code and expiration date. Records shall be readily retrievable (be produced within three business days) and maintained for a period of three years.

Q9) Can the automated mechanism distribute other items?

The automated mechanism may be used to distribute other items as long as those items are not prescription medications.

Q10) Can naloxone be returned to the automated mechanism after it has been distributed?

Naloxone removed from an automated mechanism may not be returned to the mechanism, except if it was removed and subsequently restocked by an employee of the terminal distributor of dangerous drugs.

Q11) Does the law offer liability protections for entities providing naloxone for emergency use?

Division (E) of [section 4729.515](#) of the Revised Code states:

(E) An individual is not liable for or subject to any of the following for injury, death, or loss to person or property that allegedly arises from an act or omission associated with any action authorized by this section, unless the act or omission constitutes willful or wanton misconduct: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

Q12) Does the Board have a sample inspection guide for licensee's providing naloxone for emergency use?

Yes. The Board incorporated a standard set of inspection questions on this topic in the following TDDD inspection guides (see section entitled ***Distribution of Naloxone Via Automated Mechanism***):

- [Outpatient Pharmacies](#) – 4729:5-5
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