



**STATE OF  
OHIO**  
BOARD OF PHARMACY

## **Request for Public Comment - Naloxone for Emergency Use and Distribution Via Automated Mechanism**

**Issue Date: 9/24/2020**

Acting under the authority of Chapter 4729 of the Ohio Revised Code Chapter and in accordance with [HB 341](#) (133<sup>rd</sup> General Assembly), the State of Ohio Board of Pharmacy proposes the adoption of a rule regarding the maintenance of naloxone for emergency use and distribution via automated mechanisms.

Comments on the proposed rules will be accepted until close of business on **October 8, 2020**. Please send all comments to the following email address:

[RuleComments@pharmacy.ohio.gov](mailto:RuleComments@pharmacy.ohio.gov).

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#### **4729:5-3-19 - Naloxone for emergency use and distribution via automated mechanisms**

(A) As used in this rule, "tamper-evident" means 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.

(B) In accordance with section 4729.515 of the Revised Code, a terminal distributor of dangerous drugs may acquire and maintain a supply of naloxone for use in emergency situations and for distribution through an automated mechanism. The naloxone may be maintained at a location other than the location licensed as a terminal distributor of dangerous drugs.

(C) In the case of naloxone for use in emergency situations, a terminal distributor of dangerous drugs shall do all of the following:

(1) Provide instructions regarding the emergency administration of naloxone to any individual who accesses the naloxone, to include:

(a) Specific instruction to summon emergency services pursuant to division (D)(2) of section 4729.515 of the Revised Code.

(b) Procedures for administering naloxone contained within the kit, including the possible administration of multiple doses.

(c) Performing rescue breathing and the use of a face shield or other rescue breathing barrier device, which shall be provided with the naloxone.

(d) Proper method for placing an individual into the recovery position.

(2) Specify a process to be used to notify the terminal distributor that the naloxone has been accessed within a reasonable time of its being accessed, which may include **any** of the following:

(a) 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.

(b) An automated alert that notifies the terminal distributor when the emergency naloxone is accessed.

(c) Any other method approved by the Board's executive director or the director's designee.

**Commented [MC1]:** Please be advised that this is a new section of the Ohio Revised Code (ORC) established by HB 341. This section of the ORC has been included at the end of this document.

(3) 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 shall 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 that naloxone has been accessed in accordance with paragraph (C)(2) of this rule.

(4) Maintain the naloxone in accordance with the manufacturer's or distributor's instructions.

(a) All naloxone maintained for emergency use in accordance with this paragraph shall be sealed in a tamper-evident manner to ensure the integrity of the drug.

(b) 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.

(c) 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.

(5) A terminal distributor maintaining naloxone in accordance with this paragraph shall:

(a) 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.

(b) Maintain a record of the naloxone distributed for emergency use that includes the name, strength, dosage form, national drug code and expiration date. Records shall be readily retrievable and maintained for a period of three years.

(c) 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.

(6) The requirements of this paragraph shall not apply to a service entity that maintains naloxone for emergency administration in accordance section 4729.514 of the Revised Code.

(D) In the case of naloxone for distribution through an automated mechanism, a terminal distributor of dangerous drugs shall do all the following:

(1) 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.

**Commented [MC2]: NOTE FOR COMMENTERS:** At a minimum, this would require a small piece of tamper-evident tape or a sticker on the physical box of naloxone so that licensees can be aware if the drug has been opened or otherwise tampered with.

(2) Develop a process to be used to monitor and replenish the inventory of naloxone maintained in the automated mechanism, which may include **any** of the following:

(a) Documented checks of the mechanism, to be conducted at least every thirty days, by an employee of the terminal distributor of dangerous drugs.

(b) An electronic system to monitor the inventory of naloxone within the mechanism.

(c) Any other method approved by the Board's executive director or the director's designee.

(3) Provide written educational materials appropriate to the dosage form of naloxone distributed, 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, 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.

(e) Information on naloxone.

(f) Procedures for administering naloxone.

(g) Proper storage and expiration of naloxone product distributed.

(h) Information on where to obtain a referral for substance abuse treatment.

(i) Information, as required in paragraph (D)(4) of this rule, 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.

(4) Provide a telephone number where individuals can call representatives with the requisite training necessary to answer questions regarding naloxone administration.

(5) Maintain the naloxone in accordance with the manufacturer's or distributor's instructions.

(a) Any naloxone that shows sign of tampering or adulteration shall be immediately removed by the terminal distributor of dangerous drugs.

(b) 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.

(6) A terminal distributor maintaining naloxone in accordance with this paragraph shall:

(a) 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.

(b) 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 and maintained for a period of three years.

(7) Naloxone removed from an automated mechanism shall not be returned to the mechanism or transferred in accordance with rule 4729:5-3-09 of the Administrative Code, except if it was removed by an employee of the terminal distributor of dangerous drugs.

(E) The state board of pharmacy may grant variances from this rule in cases in which:

(1) The applicable provision is not statutorily mandated.

(2) Granting the variance would not:

(a) Be contrary to public interest; or

(b) Compromise the integrity of the drug.

(3) No party will be injured by the granting of the variance.

(F) An approval for a variance pursuant to paragraph (E) of this rule may be revocable, may be granted for a limited period or may be granted subject to the conditions as the state board of pharmacy may prescribe.

(G) No licensed terminal distributor of dangerous drugs shall engage in the retail sale or other distribution of dangerous drugs or investigational drugs or products or maintain possession, custody, or control of dangerous drugs or investigational drugs or products for any purpose other than the distributor's personal use or consumption, at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal distributor.

(H) Nothing in this section shall be construed to interfere with the performance of official duties by any law enforcement official authorized by municipal, county, state, or federal law to collect samples of any drug, regardless of its nature or in whose possession it may be.

(I) Notwithstanding anything to the contrary in this section, the board of education of a city, local, exempted village, or joint vocational school district may distribute epinephrine autoinjectors for use in accordance with section 3313.7110 of the Revised Code and may distribute inhalers for use in accordance with section 3313.7113 of the Revised Code.

Sec. 4729.514. (A) As used in this section, "service entity" means a public or private entity that may provide services to or interact with individuals who there is reason to believe may be at risk of experiencing an opioid-related overdose. "Service entity" includes a church or other place of worship, college or university, school, ~~health library~~ health department operated by the board of health of a city or general health district, community addiction services provider, court, probation department, halfway house, prison, jail, community residential center, homeless shelter, or similar entity.

(B) A service entity may procure and maintain naloxone for either or both of the following purposes:

(1) To use in emergency situations;

(2) To permit an employee, volunteer, or contractor of the service entity to personally furnish a supply of naloxone pursuant to a protocol established under section 3707.561, 4723.485, 4730.435, or 4731.941 of the Revised Code.

(C) A service entity or an employee, volunteer, or contractor of a service entity 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 procuring, maintaining, accessing, ~~or using, or personally furnishing~~ naloxone under 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.

This section does not eliminate, limit, or reduce any other immunity or defense that a service entity or an employee, volunteer, or contractor of a service entity may be entitled to under Chapter 2305, or any other provision of the Revised Code or under the common law of this state.

Sec. 4729.515. (A) In accordance with divisions (B) and (C) of this section, a terminal distributor of dangerous drugs may acquire and maintain a supply of naloxone for use in emergency situations and for distribution through an automated mechanism. The naloxone may be maintained at a location other than the location licensed as a terminal distributor of dangerous drugs.

(B) In the case of naloxone for use in emergency situations, a terminal distributor of dangerous drugs shall do all of the following:

(1) Provide instructions regarding the emergency administration of naloxone to any individual who accesses the naloxone, including a specific instruction to summon emergency

services as set forth in division (D) of this section.

(2) Specify a process to be used to notify the terminal distributor that the naloxone has been accessed within a reasonable time of its being accessed.

(3) Maintain the naloxone in accordance with the manufacturer's or distributor's instructions.

(C) In the case of naloxone for distribution through an automated mechanism, a terminal distributor of dangerous drugs shall comply with standards and procedures specified in rules adopted under division (F) of this section.

(D)(1) Notwithstanding any conflicting provision of the Revised Code, both of the following apply:

(a) Any individual may access naloxone maintained as provided in division (B) of this section and may administer it to an individual who there is reason to believe is experiencing an opioid-related overdose.

(b) Any individual may receive naloxone distributed through an automated system as provided in division (C) of this section and may administer it to an individual who there is reason to believe is experiencing an opioid-related overdose.

(2) An individual who administers naloxone as authorized by this section shall make a good faith effort to activate or have another individual activate an emergency medical services system as soon as possible, except that this requirement does not apply if the individual administering the naloxone is doing so as part of an emergency medical services system or at a hospital, as defined in section 3727.01 of the Revised Code.

(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.

(F) The state board of pharmacy shall adopt rules establishing standards and procedures applicable to the distribution of naloxone through an automated mechanism. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

Sec. 4729.541. (A) Except as provided in divisions (B) to (D) of this section, all of the following are exempt from licensure as a terminal distributor of dangerous drugs:

(1) A licensed health professional authorized to prescribe drugs;

(2) A business entity that is a corporation formed under division (B) of section 1701.03 of the Revised Code, a limited liability company formed under Chapter 1705. of the Revised Code, or a professional association formed under Chapter 1785. of the Revised Code if the entity has a sole shareholder who is a prescriber and is authorized to provide the professional services being offered by the entity;

(3) A business entity that is a corporation formed under division (B) of section 1701.03 of the Revised Code, a limited liability company formed under Chapter 1705. of the Revised Code, a partnership or a limited liability partnership formed under Chapter 1775. of the Revised Code, or a professional association formed under Chapter 1785. of the Revised Code, if, to be a shareholder, member, or partner, an individual is required to be licensed, certified, or otherwise legally authorized under Title XLVII of the Revised Code to perform the professional service provided by the entity and