Ohio Administrative Code

Rule 4729:5-3-19 Naloxone for emergency use and distribution via automated mechanisms.

Effective: April 1, 2021

(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 written materials 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. The terminal distributor shall include a telephone number where persons can report that the emergency naloxone has been used and needs replenishment.

(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.

(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) Keep a record of the naloxone maintained 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.

(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 Boards executive director or the director's designee.

(3) 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:

(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.