

PHARMACY BOARD [657]

Emergency Adoption after Notice

Pursuant to the authority of Iowa Code section 147.76, the Pharmacy Board hereby amends Chapter 8, “Universal Practice Standards,” Iowa Administrative Code.

The adopted rules implement 2016 Iowa Acts, Senate File 2218, as amended by House File 2460, division XIV, which permits the possession and administration of opioid antagonist medications by certain eligible persons and allows the distribution of such medications by pharmacists pursuant to a standing order or collaborative agreement or pursuant to a prescription issued in the name of a law enforcement agency, fire department, or emergency medical service program. The amendments also remove the requirement for a pharmacy to include the address of a facility, school district, or accredited nonpublic school on the label of epinephrine dispensed to those entities.

Notice of Intended Action was published in the Iowa Administrative Bulletin as **ARC 2721C** on September 28, 2016.

The board received two comments regarding these amendments. The Iowa Medical Society submitted a comment in support of the rulemaking. The Iowa Pharmacy Association submitted comments in support of the rulemaking but with suggested modifications specifically related to the reporting requirements. The requirement of a pharmacy to submit the assessment form to the Iowa Department of Public Health (“Department”) for the purpose of data analysis was directly from the Department and the Board worked collaboratively with the Department to determine the best means for submission of the data for the Department’s analysis. The only non-substantive change made as a result of these comments comes in subrule 8.31(8) to make clear that the assessment form is provided by the Board. The adopted rules also reflect the original

language approved by the Board in its Notice of Intended Action with respect to the individual eligible to obtain an opioid antagonist pursuant to a standing order. One definition was added to provide clarity.

Pursuant to Iowa Code section 17A.5(2)“b”(2), the Pharmacy Board finds that the normal effective date of these amendments, 35 days after publication, should be waived and the amendments be made effective upon filing because the rules confer a benefit on the general public at risk of opioid-related overdose. The rules further authorize a pharmacist to dispense opioid antagonists in a manner not normally authorized for the dispensing of prescription drug products and provide procedures and recordkeeping requirements related to such dispensing.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

The Pharmacy Board adopted these amendments on November 2, 2016.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement 2016 Iowa Acts, Senate File 2218, as amended by House File 2460, division XIV.

These amendments become effective _____.

The following amendments are adopted.

ITEM 1. Amend subrule 8.19(1) as follows:

8.19(1) Requirements for a prescription. A valid prescription drug order shall be based on a valid patient-prescriber relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors and in subrule 8.19(8) for opioid antagonists.

a. to d. No change.

ITEM 2. Amend subrule 8.19(7) as follows:

8.19(7) *Epinephrine auto-injector prescription issued to school or facility.* A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more epinephrine auto-injectors in the name of a facility as defined in Iowa Code subsection 135.185(1), a school district, or an accredited nonpublic school. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the facility, the school district, or the accredited nonpublic school in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy's patient profile and record of dispensing of a prescription issued pursuant to this subrule shall be maintained in the name of the facility, school district, or accredited nonpublic school to which the prescription was issued and the drug was dispensed.

b. The label affixed to an epinephrine auto-injector dispensed pursuant to this subrule shall identify the name ~~and address~~ of the facility, school district, or accredited nonpublic school to which the prescription is dispensed.

ITEM 3. Adopt the following **new** subrule 8.19(8):

8.19(8) *Opioid antagonist prescription issued to law enforcement, fire department, or service program.* A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more opioid antagonists in the name of a law enforcement agency, fire department, or service program pursuant to Iowa Code section 147A.18 and rule 657—8.31(135,147A). The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the law enforcement agency, fire department, or service program in lieu of the

name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy's patient profile and record of dispensing of an opioid antagonist pursuant to this subrule shall be maintained in the name of the law enforcement agency, fire department, or service program to which the prescription was issued and the drug was dispensed.

b. The label affixed to an opioid antagonist dispensed pursuant to this subrule shall identify the name of the law enforcement agency, fire department, or service program to which the prescription is dispensed and shall be affixed such that the expiration date of the drug is not rendered illegible.

ITEM 4. Adopt the following new rule 657—8.31(135,147A):

657—8.31(135,147A) Opioid antagonist dispensing by pharmacists by standing order. An authorized pharmacist may dispense an opioid antagonist pursuant to a standing order established by the department, which standing order can be found via the board's Web site, or pursuant to a standing order authorized by an individual licensed health care professional in compliance with the requirements of this rule. An authorized pharmacist may only delegate the dispensing of an opioid antagonist to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist. Nothing in this rule prohibits a prescriber or facility from establishing and implementing standing orders or protocols under the authority granted to the prescriber or facility.

8.31(1) Definitions. For the purposes of this rule, the following definitions shall apply:

“Authorized pharmacist” means an Iowa-licensed pharmacist who has completed the training requirements of this rule. *“Authorized pharmacist”* also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct

supervision of an authorized Iowa-licensed pharmacist.

“Department” means the Iowa department of public health.

“First responder” means an emergency medical care provider, a registered nurse staffing an authorized service program under Iowa Code section 147A.12, a physician assistant staffing an authorized service program under Iowa Code section 147A.13, a fire fighter, or a peace officer as defined in Iowa Code section 801.4 who is trained and authorized to administer an opioid antagonist.

“Licensed health care professional” means a person licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, an advanced registered nurse practitioner licensed under Iowa Code chapter 152 or 152E and registered with the board of nursing, or a physician assistant licensed to practice under the supervision of a physician as authorized in Iowa Code chapters 147 and 148C.

“Opioid antagonist” means the same as defined in Iowa Code section 147A.1 as amended by 2016 Iowa Acts, Senate File 2218.

“Opioid-related overdose” means the same as defined in Iowa Code section 147A.1 as amended by 2016 Iowa Acts, Senate File 2218.

“Person in a position to assist” means a family member, friend, caregiver, health care provider, employee of a substance abuse treatment facility, or other person who may be in a position to render aid to a person at risk of experiencing an opioid-related overdose.

“Recipient” means an individual at risk of an opioid-related overdose or a person in a position to assist an individual at risk of an opioid-related overdose.

“Standing order” means a preauthorized medication order with specific instructions from the licensed health care professional to dispense a medication under clearly defined circumstances.

8.31(2) *Authorized pharmacist training and continuing education.* An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to opioid antagonist utilization prior to dispensing opioid antagonists pursuant to a standing order. An authorized pharmacist shall maintain competency by completing and maintaining documentation of completion of at least one hour of continuing education in opioid antagonist utilization every pharmacist license renewal period to continue eligibility to dispense opioid antagonists pursuant to a standing order.

8.31(3) *Additional supply.* Notwithstanding a standing order to the contrary, an authorized pharmacist shall only dispense an opioid antagonist after completing an eligibility assessment and providing training and education to the recipient.

8.31(4) *Assessment.* An authorized pharmacist shall assess an individual for eligibility to receive an opioid antagonist pursuant to a standing order. In addition to the criteria identified in a standing order, an authorized pharmacist shall also take into consideration the following criteria to determine the eligibility of the recipient to receive and possess an opioid antagonist:

a. The person at risk of an opioid-related overdose for which the opioid antagonist is intended to be administered has no known sensitivity or allergy to naloxone, unless the person at risk is not known to the recipient, including but not limited to a first responder or member of law enforcement.

b. The recipient is oriented to person, place, and time and able to understand and learn the essential components of opioid-related overdose, appropriate response, and opioid antagonist administration.

8.31(5) *Recipient training and education.* Upon assessment and determination that an individual is eligible to receive and possess an opioid antagonist pursuant to a standing order, an

authorized pharmacist shall, prior to dispensing an opioid antagonist pursuant to a standing order, provide training and education to the recipient that includes, but is not limited to, the information identified in this subrule. An authorized pharmacist shall require the recipient to attest that, if the product will be accessible to any other individual for administration, the recipient will make available to such individual all received training and education materials. An authorized pharmacist may provide to the recipient written materials that include, but may not be limited to, the information identified in this subrule, but it shall not be in lieu of direct pharmacist consultation with the recipient.

- a.* The signs and symptoms of opioid-related overdose as described in the standing order.
- b.* The importance of calling 911 as soon as possible and the potential need for rescue breathing.
- c.* The appropriate use and directions for administration of the opioid antagonist to be dispensed pursuant to the standing order.
- d.* Adverse reactions of the opioid antagonist as well as reactions resulting from opioid withdrawal following administration.
- e.* The proper storage conditions, including temperature excursions, of the opioid antagonist being dispensed.
- f.* The expiration date of the opioid antagonist being dispensed and the appropriate disposal of the opioid antagonist upon expiration.
- g.* The prohibition of the recipient from further distributing the opioid antagonist to another individual, unless that individual has received appropriate training and education.
- h.* Information about substance abuse or behavioral health treatment programs.

8.31(6) Labeling. Upon the determination that a recipient is eligible to receive and possess an

opioid antagonist, an authorized pharmacist shall label the product pursuant to rule 657—6.10(126,155A) and subrule 8.19(8). An authorized pharmacist shall ensure that the labeling does not render the expiration date of the product illegible. The medication shall be dispensed in the name of the eligible recipient.

8.31(7) Reporting. A copy of the assessment form shall be submitted to the department as provided on the assessment form within seven days of the dispensing of the opioid antagonist or within seven days of a denial of eligibility.

8.31(8) Records. An authorized pharmacist shall create and maintain an original record of each individual assessment on forms provided by the board, regardless of the eligibility determination following assessment, and dispensing of opioid antagonists pursuant to a standing order. These records shall be available for inspection and copying by the board or its authorized agent for at least two years.