

**PHARMACY BOARD[657]**

**Adopted and Filed**

**Rule making related to statewide protocols**

The Board of Pharmacy hereby amends Chapter 39, “Expanded Practice Standards,” Iowa Administrative Code.

*Legal Authority for Rule Making*

This rule making is adopted under the authority provided in Iowa Code sections 147.76 and 155A.46.

*State or Federal Law Implemented*

This rule making implements, in whole or in part, Iowa Code section 155A.46 and 2018 Iowa Acts, Senate File 2322, section 8.

*Purpose and Summary*

These amendments establish that a pharmacist may participate in a statewide protocol developed by the Board in consultation with the Department of Public Health; establish the minimum requirements for participation in statewide protocols, including required pharmacist training and education and required notification to the patient’s primary care provider of the product dispensed pursuant to the statewide protocol; require that the continuing education for immunization administration be approved by the Accreditation Council for Pharmacy Education (ACPE) with the specific topic designator of “06” for pharmacists; and identify a repeal date for vaccine administration by pharmacists via a physician-signed protocol in compliance with 2018 Iowa Acts, Senate File 2322, section 8.

*Public Comment and Changes to Rule Making*

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on October 24, 2018, as **ARC 4096C**.

The Board received three comments from the public. The Iowa Pharmacy Association (IPA) strongly encouraged the Board to be less prescriptive of requirements in rule and to instead include such requirements, such as minimum training and education for participation, in a statewide protocol directly. The Board appreciates the concern related to potential delays in implementing new statewide protocols as they become legislatively authorized due to rule making but also appreciates the input and feedback that comes through the rule-making review process, including from the Governor’s office, the Administrative Rules Review Committee, and the general public, particularly since these statewide protocols are being newly implemented in Iowa. The Health & Safety Institute (HSI) requested that the Board consider amended language that includes basic life support training provided by HSI for the minimum requirement of CPR training of pharmacists providing immunizations. The Board agreed to amend language that does not specify particular training providers but instead identifies the general minimum components of an acceptable training program. A third comment was received from an Iowa pharmacist who stated that pharmacists should be required to report the administration of influenza vaccines to the statewide immunization registry. The Board declined to make any changes from the proposed amendments in response to that comment since Iowa Code section 155A.44, which provides for the affected rule (relating to immunizations pursuant to a physician-signed protocol), will be repealed July 1, 2019, and the rule does not prohibit a pharmacist from voluntarily reporting influenza administrations to the statewide registry if one so chooses. The pharmacist also recommended that the continuing education requirement for participation in the naloxone statewide protocol be expanded to require repeat education each renewal period. The Board declined this suggestion to maintain

consistency with current rules relating to a pharmacist's participation in the statewide standing order to dispense naloxone.

As noted, the Board amended language relating to the training programs for basic life support to provide the core required elements of a program rather than identify specific providers.

#### *Adoption of Rule Making*

This rule making was adopted by the Board on January 9, 2019.

#### *Fiscal Impact*

This rule making has no fiscal impact to the State of Iowa.

#### *Jobs Impact*

After analysis and review of this rule making, no impact on jobs can be determined.

#### *Waivers*

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

#### *Review by Administrative Rules Review Committee*

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

#### *Effective Date*

This rule making will become effective on March 6, 2019.

The following rule-making actions are adopted:

ITEM 1. Adopt the following **new** rule 657—39.6(155A):

**657—39.6(155A) Statewide protocols.** A pharmacist may, pursuant to statewide protocols developed by the board in consultation with the department of public health and available on the board's website at [pharmacy.iowa.gov](http://pharmacy.iowa.gov), prescribe and dispense medications pursuant to rules 657—39.8(155A), 657—39.9(155A), and 657—39.11(155A).

ITEM 2. Adopt the following **new** rule 657—39.8(155A):

**657—39.8(155A) Statewide protocol—naloxone.** An authorized pharmacist may prescribe and dispense naloxone to patients 18 years and older pursuant to a statewide protocol developed pursuant to rule 657—39.6(155A) and in compliance with this rule. An authorized pharmacist may only delegate the dispensing of naloxone to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist.

**39.8(1) Definitions.** For the purposes of this rule, the following definitions shall apply:

“ACPE” means the Accreditation Council for Pharmacy Education.

“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 pharmacist.

“*Authorized pharmacist-intern*” means an Iowa-registered pharmacist-intern who has completed the training requirements for an authorized pharmacist pursuant to this rule.

“*Board*” means the Iowa board of pharmacy.

“*Patient*” means an individual consulting with a pharmacist for drug therapy and may include an individual in a position to assist someone at risk of an opioid-related overdose.

**39.8(2) *Authorized pharmacist training.*** An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to naloxone utilization prior to dispensing naloxone pursuant to the statewide protocol.

**39.8(3) *Assessment.*** An authorized pharmacist shall assess a patient for eligibility to receive naloxone using criteria identified in the statewide protocol.

**39.8(4) *Patient education.*** Upon assessment and determination that a patient is eligible to receive and possess naloxone pursuant to the statewide protocol, an authorized pharmacist shall, prior to dispensing naloxone pursuant to the statewide protocol, provide training and education to the patient including, but not limited to, the information identified in this subrule. An authorized pharmacist may provide to the patient written materials that include, but may not be limited to, the information identified in this subrule, but the written materials shall not be in lieu of direct pharmacist consultation with the patient.

a. The signs and symptoms of opioid-related overdose as described in the statewide protocol.

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 naloxone to be dispensed pursuant to the statewide protocol.

d. Adverse reactions of naloxone as well as reactions resulting from opioid withdrawal following administration.

e. The proper storage conditions, including temperature excursions, of the naloxone product being dispensed.

f. The expiration date of the naloxone product being dispensed and the appropriate disposal of the naloxone product upon expiration.

g. Information about substance abuse or behavioral health treatment programs, if applicable.

**39.8(5) *Labeling.*** Naloxone dispensed pursuant to this rule shall be labeled in accordance with rule 657—6.10(126,155A), and the labeling shall not render the expiration date of the product illegible.

**39.8(6) *Reporting.*** As soon as reasonably possible, the authorized pharmacist shall notify the patient’s primary health care provider of the naloxone product provided to the patient. If the patient does not have a primary health care provider, the authorized pharmacist shall provide the patient with a written record of the naloxone product provided to the patient and shall advise the patient to consult a physician.

**39.8(7) *Records.*** An authorized pharmacist shall maintain records of naloxone prescribed and dispensed pursuant to the statewide protocol.

ITEM 3. Adopt the following **new** rule 657—39.9(155A):

**657—39.9(155A) Statewide protocol—nicotine replacement tobacco cessation products.** An authorized pharmacist may prescribe and dispense nicotine replacement tobacco cessation products to patients 18 years and older pursuant to a statewide protocol developed pursuant to rule 657—39.6(155A) and in compliance with this rule. An authorized pharmacist may only delegate the dispensing of a nicotine replacement tobacco cessation product to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist.

**39.9(1) *Definitions.*** For the purposes of this rule, the following definitions shall apply:

“*ACPE*” means the Accreditation Council for Pharmacy Education.

“*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 pharmacist.

“*Authorized pharmacist-intern*” means an Iowa-registered pharmacist-intern who has completed the training requirements for an authorized pharmacist pursuant to this rule.

“*Board*” means the Iowa board of pharmacy.

**39.9(2) *Authorized pharmacist training.*** An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to nicotine replacement tobacco cessation product utilization prior to dispensing such products under the statewide protocol.

**39.9(3) *Assessment.*** An authorized pharmacist shall assess a patient for appropriateness of receiving a nicotine replacement tobacco cessation product pursuant to the statewide protocol.

**39.9(4) *Patient counseling and instructions.*** Upon assessment and determination that provision of the nicotine replacement tobacco cessation product is appropriate pursuant to the statewide protocol, an authorized pharmacist shall, prior to dispensing such product, provide counseling and instructions to the patient pursuant to rule 657—6.14(155A).

**39.9(5) *Labeling.*** Nicotine replacement tobacco cessation products dispensed pursuant to this rule shall be labeled in accordance with rule 657—6.10(126,155A), and the labeling shall not render the expiration date of the product illegible.

**39.9(6) *Reporting.*** As soon as reasonably possible, the authorized pharmacist shall notify the patient’s primary health care provider of the nicotine replacement tobacco cessation product provided to the patient. If the patient does not have a primary health care provider, the authorized pharmacist shall provide the patient with a written record of the nicotine replacement tobacco cessation product provided to the patient and shall advise the patient to consult a physician.

**39.9(7) *Records.*** An authorized pharmacist shall maintain records of nicotine replacement tobacco cessation products prescribed and dispensed pursuant to the statewide protocol.

ITEM 4. Amend rule 657—39.10(155A) as follows:

**657—39.10(155A) Vaccine administration by pharmacists—physician-approved protocol.** ~~An~~ Through June 30, 2019, an authorized pharmacist may administer vaccines pursuant to protocols established by the CDC in compliance with the requirements of this rule. An authorized pharmacist may only delegate the administration of a vaccine to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

**39.10(1)** No change.

**39.10(2) *Authorized pharmacist training and continuing education.*** An authorized pharmacist shall document successful completion of the requirements in paragraph 39.10(2)“a” and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 39.10(2)“b.”

*a. Initial qualification.* An authorized pharmacist shall have successfully completed an organized course of study in a college or school of pharmacy or an ACPE-accredited continuing education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in ~~the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol~~ basic cardiac life support through a training program designated for health care providers that includes hands-on training.

(2) No change.

*b. Continuing education.* During any pharmacist license renewal period, an authorized pharmacist who engages in the administration of vaccines shall complete and document at least one hour of ACPE-approved continuing education ~~related to vaccines.~~ with the ACPE topic designator “06” followed by the letter “P.”

*c. Certification maintained.* During any period within which the pharmacist may engage in the administration of vaccines, the pharmacist shall maintain current certification in ~~the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol~~ basic cardiac life support through a training program designated for health care providers that includes hands-on training.

**39.10(3) to 39.10(6)** No change.

**39.10(7) Verification and reporting.** The requirements of this subrule do not apply to influenza and other emergency vaccines administered via protocol pursuant to subrule 39.10(4). An authorized pharmacist shall:

a. No change.

b. ~~Within 30 days~~ As soon as reasonably possible following administration of a vaccine identified in subrule 39.10(5) or 39.10(6), report the vaccine administration to the statewide immunization registry or health information network and to the patient's primary health care provider, if known.

ITEM 5. Adopt the following **new** rule 657—39.11(155A):

**657—39.11(155A) Vaccine administration by pharmacists—statewide protocol.** An authorized pharmacist may prescribe and administer vaccines and immunizations pursuant to a statewide protocol developed pursuant to rule 657—39.6(155A) and in compliance with this rule. An authorized pharmacist may only delegate the prescribing and administration of a vaccine to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist.

**39.11(1) Definitions.** For the purposes of this rule, the following definitions shall apply:

“ACIP” means the CDC Advisory Committee on Immunization Practices.

“ACPE” means the Accreditation Council for Pharmacy Education.

“Authorized pharmacist” means an Iowa-licensed pharmacist who has met the requirements identified in subrule 39.11(3).

“Authorized pharmacist-intern” means an Iowa-registered pharmacist-intern who has met the requirements for an authorized pharmacist identified in subrule 39.11(3).

“Board” means the Iowa board of pharmacy.

“CDC” means the United States Centers for Disease Control and Prevention.

“Immunization” shall have the same meaning as, and shall be interchangeable with, the term “vaccine.”

“Vaccine” means a specially prepared antigen administered to a person for the purpose of providing immunity.

**39.11(2) Vaccines authorized by statewide protocol.** The vaccines authorized to be prescribed and administered pursuant to the statewide protocol shall include:

a. To patients ages 18 years and older:

(1) An immunization or vaccination recommended by ACIP in its approved vaccination schedule for adults.

(2) An immunization or vaccination recommended by CDC for international travel.

(3) A Tdap (tetanus, diphtheria, acellular pertussis) vaccination in a booster application.

(4) Other emergency immunizations or vaccinations in response to a public health emergency.

b. To patients ages six months and older:

(1) A vaccine or immunization for influenza.

(2) Other emergency immunizations or vaccines in response to a public health emergency.

c. To patients ages 11 years and older:

(1) The final two doses in a course of vaccinations for human papillomavirus (HPV).

(2) Reserved.

**39.11(3) Authorized pharmacist training and continuing education.** An authorized pharmacist shall document successful completion of the requirements in paragraph 39.11(3) “a” and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 39.11(3) “b.”

a. *Initial qualification.* An authorized pharmacist shall have successfully completed an organized course of study in a college or school of pharmacy or an ACPE-accredited continuing education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

(2) Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current CDC guidelines, and provides instruction and experiential training in the following content areas:

1. Standards for immunization practices;
2. Basic immunology and vaccine protection;
3. Vaccine-preventable diseases;
4. Recommended immunization schedules;
5. Vaccine storage and management;
6. Informed consent;
7. Physiology and techniques for vaccine administration;
8. Pre- and post-vaccine assessment, counseling, and identification of contraindications to the vaccine;
9. Immunization record management; and
10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

*b. Continuing education.* During any pharmacist license renewal period, an authorized pharmacist who engages in the administration of vaccines shall complete and document at least one hour of ACPE-approved continuing education with the ACPE topic designator “06” followed by the letter “P.”

*c. Certification maintained.* During any period within which the pharmacist may engage in the administration of vaccines, the pharmacist shall maintain current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

**39.11(4) Assessment.** An authorized pharmacist shall assess a patient for appropriateness of receiving a vaccine pursuant to the statewide protocol.

**39.11(5) Verification and reporting.** Prior to the prescribing and administration of an immunization pursuant to the statewide protocol, the authorized pharmacist shall consult and review the statewide immunization registry or health information network. As soon as reasonably possible following administration of a vaccine, the pharmacist shall report such administration to the patient’s primary health care provider, primary physician, and a statewide immunization registry or health information network. If the patient does not have a primary health care provider, the pharmacist shall provide the patient with a written record of the vaccine administered to the patient and shall advise the patient to consult a physician.

ITEM 6. Amend **657—Chapter 39**, implementation sentence, as follows:

These rules are intended to implement Iowa Code sections 135.190, 147.76, 147A.18, 155A.2, 155A.3, 155A.13, 155A.33, and 155A.44; 2018 Iowa Acts, Senate File 2322; and 2011 Iowa Acts, chapter 63, section 36, as amended by 2012 Iowa Acts, chapter 1113, section 31, and by 2013 Iowa Acts, chapter 138, section 128.

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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 1/30/19.