

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76 and 2013 Iowa Acts, Senate File 353, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 8, “Universal Practice Standards,” Iowa Administrative Code.

The amendment was approved at the June 26, 2013, regular meeting of the Board of Pharmacy.

The proposed amendment rescinds current rule 657—8.33(147,155A) and adopts new rule 657—8.33(155A). The proposed rule establishes training and continuing education requirements for pharmacists engaged in the administration of vaccines and immunizations, identifies the vaccines and immunizations that a qualified pharmacist may administer to patients within specified age categories, and requires compliance with and utilization of the United States Centers for Disease Control and Prevention’s (CDC) protocol for the administration of vaccines and immunizations.

The proposed rule also requires the pharmacist, prior to administering a vaccine or immunization on the approved adult vaccination schedule of the CDC Advisory Committee on Immunization Practices, a vaccine or immunization recommended by the CDC for international travel, or a vaccine or immunization to be administered pursuant to a prescription or medication order for an individual patient, to consult with the statewide immunization registration or health information network. The proposed rule requires the pharmacist to report the administration of a vaccine or immunization described in this paragraph to the statewide immunization registry or health information network and to the patient’s primary health care provider, if known, within 30 days of the administration.

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

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on August 13, 2013. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

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

This amendment is intended to implement Iowa Code sections 155A.3 and 155A.4 and 2013 Iowa Acts, Senate File 353.

The following amendment is proposed.

Rescind rule 657—8.33(147,155A) and adopt the following **new** rule in lieu thereof:

657—8.33(155A) Vaccine and immunization administration by pharmacists. An authorized pharmacist may administer vaccines and immunizations pursuant to protocols established by the CDC in compliance with the requirements of this rule.

8.33(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 8.33(2).

“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.”

“Protocol” means a standing order for a vaccine or immunization to be administered by an authorized pharmacist.

“Vaccine” means a specially prepared antigen which, upon administration to a person, will result in immunity.

8.33(2) Authorized pharmacist training and continuing education. An authorized pharmacist shall document successful completion of the requirements in paragraph 8.33(2)“a” and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 8.33(2)“b.”

a. Initial qualification. Successful completion of 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 for health care providers.

(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 and counseling;
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 continuing education related to vaccines and immunizations.

8.33(3) Protocol requirements. A pharmacist may administer vaccines pursuant to CDC protocols. Links to CDC protocols shall be provided on the board’s Web site at www.iowa.gov/ibpe. A protocol:

- a.* Shall be signed by a licensed Iowa prescriber practicing within the local provider service area.
- b.* Shall expire no later than one year from the effective date of the signed protocol.
- c.* Shall be effective for patients who wish to receive a vaccine administered by an authorized pharmacist, who meet the CDC recommended criteria, and who have no contraindications as published by the CDC.

8.33(4) Influenza and other emergency vaccines. An authorized pharmacist shall only administer via protocol, to patients six years of age and older, influenza vaccines and other emergency vaccines in response to a public health emergency.

8.33(5) Other adult vaccines. An authorized pharmacist shall only administer via protocol, to patients 18 years of age and older, the following vaccines:

- a.* A vaccine on the ACIP-approved adult vaccination schedule.
- b.* A vaccine recommended by the CDC for international travel.
- c.* A Tdap (tetanus, diphtheria, acellular pertussis) vaccination in a booster application.

8.33(6) Vaccines administered via prescription. An authorized pharmacist may administer any vaccine pursuant to a prescription or medication order for an individual patient.

8.33(7) Verification and reporting. An authorized pharmacist shall:

- a.* Prior to administering a vaccine identified in subrule 8.33(5) or subrule 8.33(6), consult the statewide immunization registry or health information network.

b. Within 30 days following administration of a vaccine identified in subrule 8.33(5) or subrule 8.33(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.