

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, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 7, “Hospital Pharmacy Practice,” Iowa Administrative Code.

The amendment was approved at the November 4, 2015, regular meeting of the Board of Pharmacy.

The proposed amendment eliminates restrictions regarding the dispensing of prescription drugs to patients seen in a hospital emergency department when 24-hour pharmacy services are available within 15 miles of the hospital. The amendment specifically authorizes the dispensing, to hospital emergency department patients, of appropriately packaged and labeled prescription drugs in quantities not exceeding a 72-hour supply except as specifically identified in subrule 7.12(3). The amendment eliminates the requirement that drugs dispensed through the emergency department only be dispensed in prepackaged quantities, clarifies that the prescriber is responsible for ensuring the drug is appropriately packaged and labeled but not that the prescriber must complete the labeling, and adds that the quantity of the drug dispensed must be included on the dispensing label.

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 December 29, 2015. 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 124.301, 155A.13, and 155A.28.

The following amendment is proposed.

Amend subrule 7.12(3) as follows:

7.12(3) Drug dispensing. ~~In those facilities with 24-hour pharmacy services, only~~ Only a pharmacist or prescriber may dispense any drugs to an emergency department patient. ~~In those facilities located in an area of the state where 24-hour outpatient or 24-hour on-call pharmacy services are not available within 15 miles of the hospital, and which facilities are without 24-hour outpatient pharmacy services, pursuant to the provisions of this rule shall apply.~~

a. Responsibility. Pursuant to rule 657—8.3(155A), the accuracy and labeling of prepackaged drugs shall be ensured and accurate records of dispensing of drugs from the emergency department shall be maintained.

(1) Prepackaging. Except as provided in subrule 7.12(4), drugs dispensed to an emergency department patient ~~in greater than a 24-hour supply~~ may be dispensed ~~only in prepackaged~~ quantities not to exceed a 72-hour supply or the minimum prepackaged quantity in suitable containers, except that a seven-day supply of doxycycline provided through the department of public health pursuant to the crime victim compensation program of the Iowa department of justice may be dispensed for the treatment of a victim of sexual assault. Prepackaged drugs shall be prepared pursuant to the requirements of rule 657—22.3(126).

(2) Labeling. Drugs dispensed pursuant to this paragraph shall be appropriately labeled as required in paragraph 7.12(3)“b,” including necessary auxiliary labels.

b. Prescriber responsibility. Except as provided in subrule 7.12(4), a prescriber who authorizes dispensing of a prescription drug to an emergency department patient is responsible for the accuracy of the dispensed drug and for the accurate completion of label information pursuant to this paragraph.

(1) Labeling. Except as provided in subrule 7.12(4), at the time of delivery of the drug the prescriber shall ~~appropriately complete the label such~~ be responsible for ensuring that the dispensing container bears a label with at least the following information:

1. Name and address of the hospital;
2. Date dispensed;
3. Name of prescriber;
4. Name of patient;
5. Directions for use;
6. Name, quantity, and strength of drug.

(2) Delivery of drug to patient. Except as provided in subrule 7.12(4), the prescriber, or a licensed nurse under the supervision of the prescriber, shall give the appropriately labeled, ~~prepackaged~~ packaged drug to the patient or patient's caregiver. The prescriber, or a licensed nurse under the supervision of the prescriber, shall explain the correct use of the drug and shall explain to the patient that the dispensing is for an emergency or starter supply of the drug. If additional quantities of the drug are required to complete the needed course of treatment, the prescriber shall provide the patient with a prescription for the additional quantities.