ARC 0652C

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 sections 124.301 and 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 10, "Controlled Substances," Chapter 22, "Unit Dose, Alternative Packaging, and Emergency Boxes," and Chapter 23, "Long-Term Care Pharmacy Practice," Iowa Administrative Code.

The amendments were approved at the January 16, 2013, regular meeting of the Board of Pharmacy.

The proposed amendments authorize a pharmacy other than a facility's primary provider pharmacy to provide to the facility to meet the needs of the facility's patients an emergency/first dose drug supply containing those drugs and products not stocked or available from the primary provider pharmacy. This additional supply may include, but is not limited to, parenteral or compounded drug products. The proposed amendments also provide that a multidose container of a drug removed from the emergency drug supply for administration to a patient be labeled with a patient-specific label within 24 hours of initial administration or that an appropriately labeled new drug order be dispensed and delivered by the provider pharmacy. The record requirements for controlled substances destroyed in a long-term care facility and for previously dispensed controlled substances destroyed by a pharmacy are amended to require the recording of the dispensing pharmacy or other source of the controlled substance and the prescription number or other unique identification assigned to the prescription.

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

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on April 9, 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.

These amendments are intended to implement Iowa Code sections 124.301, 155A.13, and 155A.15.

The following amendments are proposed.

ITEM 1. Amend subrule 10.18(3) as follows:

10.18(3) *Previously dispensed controlled substances.* Controlled substances dispensed to or for a patient and subsequently requiring destruction due to discontinuance of the drug, death of the patient, or other reasons necessitating destruction may be destroyed or otherwise disposed of by a pharmacist in witness of one other responsible adult pursuant to this subrule. All licenses and registrations issued to the pharmacy, the pharmacist, and any individual witnessing the destruction or other disposition shall not be subject to sanctions relating to controlled substances at the time of the destruction or disposition. The individuals involved in the destruction or other disposition shall not have been subject to any criminal, civil, or administrative action relating to violations of controlled substances laws, rules, or regulations within the past five years. The pharmacist in charge shall be responsible for designating pharmacists authorized to participate in the destruction or other disposition pursuant to this subrule. The authorized pharmacist shall prepare and maintain in the pharmacy a readily retrievable record of the destruction or other disposition, which shall be clearly marked to indicate the destruction or other disposition of noninventory or patient drugs. The record shall include, at a minimum, the following:

a. ~~Source~~ The source of the controlled substance (patient identifier or administering practitioner, if applicable, prescription number or other unique identification number, and date of return);

b. The name, strength, and dosage form of the substance;

c. The quantity returned and destroyed or otherwise disposed of;

d. The date the substance is destroyed or otherwise disposed of;

e. The signatures or other unique identification of the pharmacist and the witness.;

f. The name and address of the dispensing pharmacy or practitioner if the controlled substance was not dispensed by the pharmacy completing the destruction.

ITEM 2. Amend subrule 22.7(1) as follows:

22.7(1) *Emergency/first dose drug supplies.* All contents Contents of the emergency/first dose drug supply shall be provided by one a primary provider pharmacy designated by the facility, and the drug supply shall be available to meet the needs of all patients of the facility, without penalty or discrimination. If the primary provider pharmacy does not supply or is unable to supply all drugs and products needed for the emergency care of facility patients, a second provider pharmacy may provide an emergency/first dose drug supply consisting only of drugs and products not stocked or available from the primary provider pharmacy including, but not limited to, parenteral or compounded drug products. The provider pharmacy pharmacies shall be properly registered with the federal Drug Enforcement Administration (DEA) and the board and shall be currently licensed by the board. The provider pharmacist or pharmacists, the consultant pharmacist, the director of nursing of the facility, and the medical director of the facility, or their respective designees, shall jointly determine and prepare a list of drugs necessary for prompt use in patient care that will be available in the each emergency/first dose drug supply. Drugs shall be listed by identity and quantity, shall be limited to drugs necessary to meet the emergency needs of the patients served, and shall be periodically reviewed pursuant to policy. Careful patient planning should be a cooperative effort between the pharmacy pharmacies and the facility to make drugs available, and this supply emergency/first dose drug supplies shall only be used for emergency or unanticipated needs. The intent of the emergency/first dose drug supply is not to relieve a pharmacy of the responsibility for timely provision of a patient's routine drug needs and is not intended to relieve any provider pharmacy from the provider pharmacy's responsibility to provide 24-hour services to facility patients; the intent is to ensure that a supply of drugs is available to each patient in case of urgent need. The drugs in the emergency/first dose drug supply supplies are the responsibility of the respective provider pharmacy and, therefore, shall not be used or altered in any way except as provided in this rule.

ITEM 3. Amend subrule 22.7(5) as follows:

22.7(5) *Removal of drugs.* A drug shall be removed from the emergency/first dose drug supply only pursuant to a valid prescription order and by authorized personnel or by the provider pharmacist. The patient's dispensing pharmacy shall be notified, prior to the administration of a second dose, that a drug was administered to a specific patient. Upon notification, the dispensing pharmacist shall perform drug use review to assess the appropriateness of the drug therapy for the patient. If the emergency/first dose drug supply contains a multidose package of a drug product that is removed from the supply for administration of one or more doses of the product to a patient and if following that administration the package contains one or more additional doses of the drug product and if the prescriber authorizes continuation of the drug product for that patient, the provider pharmacy shall complete either of the following processes.

a. Prepare and affix to the multidose package a label in compliance with rule 657—23.11(124,155A). The label shall be prepared and affixed to the package within 24 hours of administration of the emergency dose or doses.

b. Dispense, pursuant to a valid prescription order and in compliance with rule 657—23.11(124,155A), an appropriately labeled supply of the drug for the patient. The new prescription shall be delivered to the facility within 24 hours of administration of the emergency dose or doses.

ITEM 4. Amend rule 657—23.5(124,155A) as follows:

657—23.5(124,155A) Emergency drugs. A supply of emergency drugs may be provided by one or more long-term care pharmacy provider pharmacies to the facility pursuant to rule 657—22.7(124,155A).

23.5(1) *Emergency medication order—pharmacist review.* When an emergency drug is provided pursuant to rule 657—22.7(124,155A), the medication order shall be reviewed by the resident's dispensing pharmacist prior to the administration of a second dose.

23.5(2) *Other emergency drugs and devices.* In addition to ~~an~~ one or more emergency ~~box~~ boxes or stat drug ~~box~~ boxes, a long-term care facility staffed by one or more persons licensed to administer drugs may maintain a stock of intravenous fluids, irrigation fluids, heparin flush kits, medicinal gases, sterile water and saline, and prescription devices. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the consultant pharmacist and the medical director and director of nursing of the facility.

ITEM 5. Amend subrule 23.21(1) as follows:

23.21(1) *Destruction in the facility.* In facilities staffed by one or more persons licensed to administer drugs, a licensed health care professional (pharmacist, registered nurse, licensed practical nurse) may destroy controlled substances in witness of one other responsible adult. The professional destroying or otherwise disposing of the drug shall prepare and maintain a readily retrievable record of the destruction or other disposition which shall be clearly marked to indicate the destruction or other disposition of resident drugs. The record shall include, at a minimum, the following:

a. Resident name and unique identification or number assigned by the dispensing pharmacy to the prescription;

b. The name, strength, and dosage form of the substance;

c. The quantity destroyed or otherwise disposed of;

d. The date the substance is destroyed or otherwise disposed of;

e. The signature or uniquely identifying initials or other unique identification of the professional and the witness~~.~~;

f. The name and address of the dispensing pharmacy or the dispensing practitioner.