ARC 2285C

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 6, "General Pharmacy Practice," Chapter 7, "Hospital Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 10, "Controlled Substances," Chapter 17, "Wholesale Drug Licenses," and Chapter 23, "Long-term Care Pharmacy Practice," Iowa Administrative Code.

The amendments were approved at the November 4, 2015, regular meeting of the Board of Pharmacy.

The proposed amendments incorporate into Board rules updated federal regulations, finalized in October 2014, authorizing certain registrants to voluntarily administer an authorized collection program to collect unwanted controlled substances from patients for the purpose of disposal. The amendments also rescind rules that are in conflict with federal regulations and that would otherwise prohibit such collection activities.

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 amendments 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.

These amendments are intended to implement Iowa Code section 124.301.

The following amendments are proposed.

ITEM 1. Amend rule 657—6.7(124,155A), introductory paragraph, as follows:

657—6.7(124,155A) Security. While on duty, each pharmacist shall be responsible for the security of the prescription department~~, including~~ and of the provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program, records for such drugs and authorized collection program activities, and patient records as provided in 657—~~Chapter~~ Chapters 10 and 21 and federal regulations for authorized controlled substance collection programs, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

ITEM 2. Amend rule 657—7.6(124,155A) as follows:

657—7.6(124,155A) Security. The pharmacy shall be located in an area or areas that facilitate the provision of services to patients and shall be integrated with the facility's communication and transportation systems. The following conditions must be met to ensure appropriate control over drugs and chemicals in and under the control of the pharmacy:

7.6(1) to **7.6(5)** No change.

7.6(6) *Authorized collection program.* Receptacles that are located in the hospital for the authorized collection of controlled substances shall be secured pursuant to 657—Chapter 10 and federal regulations for disposal of controlled substances. Federal regulations regarding disposal of controlled substances can be found at http://deadiversion.usdoj.gov/drug_disposal/.

ITEM 3. Adopt the following **new** subrule 8.5(9):

8.5(9) *Authorized collection program.* A pharmacy that is registered with the United States Department of Justice, Drug Enforcement Administration, to administer an authorized collection program shall provide adequate space, equipment, and supplies for such collection program pursuant to 657—Chapter 10 and federal regulations for authorized collection programs, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

ITEM 4. Amend rule 657—10.1(124) as follows:

657—10.1(124) ~~Who shall register~~ Purpose and definitions. Any person or business located in Iowa that manufactures, distributes, dispenses, prescribes, imports or exports, conducts research or instructional activities, or conducts chemical analysis with controlled substances in the state of Iowa, or that proposes to engage in such activities with controlled substances in the state, shall obtain and maintain a registration issued by the board unless exempt from registration pursuant to rule 657—10.6(124). A person or business required to be registered shall not engage in any activity for which registration is required until the application for registration is granted and the board has issued a certificate of registration to such person or business.

10.1(1) *Who shall register.* Manufacturers, distributors, reverse distributors, importers and exporters, individual practitioners (M.D., D.O., D.D.S., D.V.M., D.P.M., O.D., P.A., resident physician, advanced registered nurse practitioner), pharmacies, hospitals and animal shelters, care facilities, researchers and dog trainers, analytical laboratories, and teaching institutions shall register on forms provided by the board office. To be eligible to register, individual practitioners must hold a current, active license in good standing, issued by the appropriate Iowa professional licensing board, to practice their profession in Iowa.

10.1(2) *Definitions.* For the purpose of this chapter, the following definitions shall apply:

"Authorized collection program" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at http://deadiversion.usdoj.gov/drug_disposal/. Modification to the registrant's Iowa Controlled Substances Act registration shall not be required.

"DEA" means the United States Department of Justice, Drug Enforcement Administration.

ITEM 5. Amend rule 657—10.6(124) as follows:

657—10.6(124) Separate registrations for separate locations; exemption from registration. A separate registration is required for each principal place of business or professional practice location where controlled substances are manufactured, distributed, imported, exported, ~~or~~ dispensed, or collected for the purpose of disposal unless the person or business is exempt from registration pursuant to Iowa Code subsection 124.302(3), ~~or~~ this rule, or federal regulations.

10.6(1) to **10.6(5)** No change.

ITEM 6. Amend subrule 10.15(1) as follows:

10.15(1) *Physical security.* Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operation. A registrant shall periodically review and adjust security measures based on rescheduling of substances or changes in the quantity of substances in the possession of the registrant.

a. and *b.* No change.

c. Controlled substances collected via an authorized collection program for the purpose of disposal shall be stored pursuant to federal regulations, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.

ITEM 7. Amend rule 657—10.18(124) as follows:

657—10.18(124) Disposal of registrant stock. Any persons legally authorized to possess controlled substances in the course of their professional practice or the conduct of their business shall dispose of

such drugs pursuant to the procedures and requirements of this rule. Disposal records shall be maintained ~~in the files of~~ by the registrant.

10.18(1) and **10.18(2)** No change.

~~**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.* 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 8. Rescind rule 657—10.19(124) and adopt the following **new** rule in lieu thereof:

657—10.19(124) Disposal of previously dispensed controlled substances. A registrant may not dispose of previously dispensed controlled substances unless the registrant has modified its registration with DEA to administer an authorized collection program. A registrant shall not take possession of a previously dispensed controlled substance except for reuse for the same patient.

ITEM 9. Amend subrule 10.34(3) as follows:

10.34(3) *Date of record.* The date on which a controlled substance is actually received, imported, distributed, exported, disposed of, or otherwise transferred shall be used as the date of receipt, importation, ~~or~~ distribution, exportation, disposal, or transfer.

ITEM 10. Amend subrule 10.35(1) as follows:

10.35(1) *Record and procedure.* Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.33(4), shall comply with the requirements of this subrule and shall be maintained for a minimum of two years from the date of the inventory.

a. and *b.* No change.

c. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant. These shall include prescriptions prepared for dispensing to a patient but not yet delivered to the patient, substances maintained in emergency medical services programs or care facility emergency supplies, outdated or adulterated substances pending destruction, and substances stored in a warehouse on behalf of the registrant. Controlled substances obtained through an authorized collection program for the purpose of disposal shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.

d. and *e.* No change.

f. The inventory record, unless otherwise provided under federal law, shall include the following information:

(1) The name of the substance;

(2) The strength and dosage form of the substance; ~~and~~

(3) The quantity of the substance.; and

(4) Information required of authorized collection programs pursuant to federal regulations for such collection programs.

g. and *h.* No change.

ITEM 11. Adopt the following **new** definitions in rule **657—17.1(155A)**:

"Authorized collection program" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at http://deadiversion.usdoj.gov/drug_disposal/. Modification to the registrant's Iowa Controlled Substances Act registration shall not be required.

"DEA" means the United States Department of Justice, Drug Enforcement Administration.

ITEM 12. Amend rule 657—17.3(155A), introductory paragraph, as follows:

657—17.3(155A) Wholesale drug license. Every wholesaler as defined in rule 657—17.1(155A), wherever located, that engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and rules of Iowa before engaging in wholesale distribution of prescription drugs. Where operations are conducted at more than one location by a single wholesaler, each such location shall be separately licensed in Iowa. A wholesaler located within Iowa that engages in wholesale distribution of or collection via an authorized collection program of controlled substances shall also register pursuant to 657—Chapter 10.

ITEM 13. Adopt the following **new** subrule 17.10(4):

17.10(4) *Authorized collection program.* Licensees that are authorized to administer a controlled substances collection program shall provide security pursuant to 657—Chapter 10 and federal regulations.

ITEM 14. Adopt the following **new** subrule 17.14(4):

17.14(4) *Authorized collection program.* Substances, including controlled substances, collected through an authorized collection program shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.

ITEM 15. Adopt the following **new** subrule 17.16(5):

17.16(5) *Authorized collection program.* A licensee that is authorized to administer a collection program shall maintain all records and inventories as required by 657—Chapter 10, this chapter, and federal regulations.

ITEM 16. Adopt the following **new** definitions in rule **657—23.1(155A)**:

"Authorized collection program" means a program administered by a registrant that has modified its registration with DEA to collect controlled substances for the purpose of disposal. Federal regulations for such programs can be found at http://deadiversion.usdoj.gov/drug_disposal/.

"DEA" means the United States Department of Justice, Drug Enforcement Administration.

ITEM 17. Amend subrule 23.11(4) as follows:

23.11(4) *Floor stock.* Prescription drugs, as defined by Iowa Code section ~~155A.3(30)~~ 155A.3(37), shall not be floor-stocked in a long-term care facility except as provided in this subrule or in subrule 23.5(2). Bulk supplies of nonprescription drugs may be maintained as provided in subrule 23.13(3). Any pharmacy that utilizes a floor stock distribution system pursuant to this subrule shall develop and implement procedures to accurately establish proof of use of prescription drugs and shall maintain a perpetual inventory, whether by electronic or manual means, of all prescription drugs so dispensed. A floor stock distribution system for prescription drugs may be permitted only under the following circumstances:

a. and *b.* No change.

ITEM 18. Amend rule 657—23.21(124,155A) as follows:

657—23.21(124,155A) ~~Destruction~~ Disposal of previously dispensed controlled substances. Controlled substances dispensed to a resident in a long-term care facility and subsequently requiring ~~destruction~~ disposal due to discontinuance of the drug, death of the resident, or other reasons necessitating ~~destruction~~ disposal shall be ~~destroyed~~ disposed of by one of the following methods. Controlled substances shall not be returned to a pharmacy for disposal.

23.21(1) ~~*Destruction*~~ *Disposal 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~~ dispose of 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.

23.21(2) ~~*Destruction or other disposition in the long-term care pharmacy*~~ *Authorized collection program within a facility.* ~~Controlled substances returned to the pharmacy for destruction or other disposition may be destroyed or otherwise disposed of pursuant to the requirements of 657—subrule 10.18(3).~~ Registrants registered with DEA to administer an authorized collection program may install and maintain a collection receptacle in a long-term care facility for the purpose of disposal of prescription drugs, including controlled substances, pursuant to federal regulations, which can be found at http://deadiversion.usdoj.gov/drug_disposal/.