ARC 7448B

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 6, "General Pharmacy Practice," Chapter 8, "Universal Practice Standards," Chapter 9, "Automated Medication Distribution Systems," Chapter 10, "Controlled Substances," and Chapter 21, "Electronic Data in Pharmacy Practice," Iowa Administrative Code.

These amendments were approved at the November 19, 2008, regular meeting of the Board of Pharmacy.

The proposed amendments require that any prescription transmitted via facsimile to a pharmacy and any electronic record maintained by a pharmacy must be clear, legible records or images of the original prescription or record. The amendments are intended to ensure that the electronic transmission or scanning of a prescription or record that was prepared in hard copy utilizing paper that includes security features, such as the appearance of a "void" message upon copying or scanning, is not rendered illegible or obscured as a result of those security features.

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 January 20, 2009. 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.

These amendments are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 155A.27, and 155A.35.

The following amendments are proposed.

ITEM 1. Amend subrule 6.16(4) as follows:

6.16(4) *Alternative data retention system.* Records, except when specifically required to be maintained in original or hard-copy form, may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

a. The records maintained in the alternative system contain all of the information required on the manual record; ~~and~~

b. The data processing system is capable of producing a hard copy of the record, within two business days, upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies ~~.~~; and

c. The information maintained in the alternative system is not obscured or rendered illegible due to security features of the original hard-copy record.

ITEM 2. Amend subrule 8.15(1) as follows:

8.15(1) *Alternative methods.* A licensed pharmacy may, by means of its employee or by use of a common carrier, pick up or deliver prescriptions to the patient or the patient's caregiver as follows:

a. At the office or home of the prescriber.

b. At the residence of the patient or caregiver.

c. At the hospital or medical care facility in which a patient is confined.

d. At an outpatient medical care facility where the patient receives treatment only pursuant to the following requirements:

(1) The pharmacy shall obtain and maintain the written authorization of the patient or patient's caregiver for receipt or delivery at the outpatient medical care facility;

(2) The prescription shall be delivered directly to or received directly from the patient, the caregiver, or an authorized agent identified in the written authorization;

(3) A prescription authorized by a prescriber not treating the patient at the outpatient medical care facility may be transmitted to the pharmacy by the authorized agent via facsimile provided that the means of transmission does not obscure or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the prescription and provided that the original written prescription is delivered to the pharmacy prior to delivery of the filled prescription to the patient; and

(4) The outpatient medical care facility shall store the patient's filled prescriptions in a secure area pending delivery to the patient.

e. At the patient's or caregiver's place of employment only pursuant to the following requirements:

(1) The pharmacy shall obtain and maintain the written authorization of the patient or patient's caregiver for receipt or delivery at the place of employment;

(2) The prescription shall be delivered directly to or received directly from the patient, the caregiver, the prescriber, or an authorized agent identified in the written authorization; and

(3) The pharmacy shall ensure the security of confidential information as defined in subrule 8.16(1).

ITEM 3. Amend subrule 9.18(7) as follows:

9.18(7) *Verification prior to dispensing.* A pharmacist at the managing pharmacy shall approve each prescription before it leaves the remote site. If the qualified certified pharmacy technician at the remote site enters original or new prescription information into the automated pharmacy system, the pharmacist at the managing pharmacy shall, prior to approving dispensing of the drug via the AMDS, verify the information entered against an electronic or video image of the original prescription. The technician may transmit the prescription to the pharmacist by scanning the prescription into the automated pharmacy system ~~or~~ provided that the means of scanning, transmitting, or storing the image shall not obscure the prescription information or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the original prescription. Alternatively, the technician may make the original prescription available to the pharmacist by placing the prescription in an appropriate position to facilitate viewing of the original prescription with video communication between the remote site and the managing pharmacy. Using the video communication component of the automated pharmacy system, the pharmacist shall verify the accuracy of the drug dispensed and shall check the prescription label for accuracy. The dispensing record, the patient profile, and the prescription label shall identify both the pharmacist who approved dispensing the prescription and the certified pharmacy technician who completed the dispensing and delivery of the prescription to the patient.

ITEM 4. Amend subrule 10.22(2) as follows:

10.22(2) *Requirements of emergency prescription.* In the case of an emergency situation as defined herein, a pharmacist may dispense a controlled substance listed in Schedule II pursuant to an electronic transmission or upon receiving oral authorization of a prescribing individual practitioner provided that:

a. The quantity prescribed and dispensed is limited to the smallest available quantity to meet the needs of the patient during the emergency period. Dispensing beyond the emergency period requires a written prescription manually signed by the prescribing individual practitioner.

b. If the pharmacist does not know the prescribing individual practitioner, the pharmacist shall make a reasonable effort to determine that the authorization came from an authorized prescriber. The pharmacist shall record the manner by which the authorization was verified and include the pharmacist's name or unique identification.

c. The pharmacist shall prepare a temporary written record of the emergency prescription. The temporary written record shall consist of a hard copy of the electronic transmission or a written record of the oral transmission authorizing the emergency dispensing. If the emergency prescription is transmitted by the practitioner's agent, the record shall include the name and title of the individual who transmitted the prescription.

d. If the emergency prescription is transmitted via electronic transmission, the means of transmission shall not obscure or render the prescription information illegible due to security features of the paper utilized by the prescriber to prepare the written prescription, and the hard-copy record of the electronic transmission shall not be obscured or rendered illegible due to such security features.

~~*d.*~~ *e.* Within seven days after authorizing an emergency prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of 657—10.21(124,126,155A), the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the emergency order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the seven-day period. The written prescription shall be attached to and maintained with the temporary written record prepared pursuant to paragraph *"c."*

~~*e.*~~ *f.* The pharmacist shall notify the board if the prescribing individual fails to deliver a written prescription. Failure of the pharmacist to so notify the board, or failure of the prescribing individual to deliver the required written prescription as herein required, shall void the authority conferred by this subrule.

ITEM 5. Amend paragraph **21.7(3)"c"** as follows:

c. When a prescription prepared pursuant to this subrule is transmitted to a pharmacy via facsimile, or when a prescription prepared pursuant to this subrule is scanned into an electronic record system, the watermark or background will not appear or the word "void" or "copy" will appear. The means of transmission via facsimile and the means of scanning into an electronic record system shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare the prescription. It is the responsibility of the pharmacist to verify the validity of the prescription as provided by rule 657—8.19(124,126,155A) or 657—21.3(124,155A).

ITEM 6. Amend rule 657—21.9(124,155A) as follows:

657—21.9(124,155A) Facsimile transmission (fax) of a prescription. A pharmacist may dispense noncontrolled and controlled drugs, excluding Schedule II controlled substances, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the practitioner's agent. The means of transmission shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription. The faxed prescription drug order shall serve as the original prescription, shall be maintained for a minimum of two years from the date of last fill or refill, and shall contain all information required by Iowa Code section 155A.27, including the prescriber's signature or electronic signature. The faxed prescription drug order, if transmitted by the practitioner's agent, shall identify the transmitting agent and shall include the prescriber's signature or electronic signature. The receiving pharmacist shall be responsible for verifying the authenticity of an electronically transmitted prescription or of an electronic signature as provided by rule 657—8.19(124,126,155A) or 657—21.3(124,155A). This rule shall apply to a prescription drug order transmitted pursuant to 657—subrule 8.15(1), paragraph *"d."*

ITEM 7. Amend rule 657—21.12(124,155A) as follows:

657—21.12(124,155A) Prescription drug orders for Schedule II controlled substances. A pharmacist may dispense Schedule II controlled substances pursuant to an electronic transmission to the pharmacy of a written, signed prescription from the prescribing practitioner provided that the original written, signed prescription is received by the pharmacist prior to the actual dispensing of the controlled substance. If the emergency authorization is transmitted to the pharmacy by the practitioner's agent, the transmission shall include the name and title of the individual who transmitted the prescription. The means of transmission shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription. The original prescription shall be verified against the transmission at the time the substance is actually dispensed, shall be properly annotated, and shall be retained with the electronic transmission for filing.

ITEM 8. Amend rule 657—21.14(124,155A) as follows:

657—21.14(124,155A) Facsimile transmission of a prescription for Schedule II narcotic substances—parenteral. A prescription for a nonoral dosage unit of a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by a practitioner or the practitioner's agent to the pharmacy via facsimile. If the prescription is transmitted by the practitioner's agent, the transmission shall include the name and title of the individual who transmitted the prescription. The means of transmission shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription. The facsimile serves as the original written prescription.

ITEM 9. Amend rule 657—21.15(124,155A), introductory paragraph, as follows:

657—21.15(124,155A) Facsimile transmission of Schedule II controlled substances—long-term care facility patients. A prescription for any Schedule II controlled substance for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy via facsimile. If the prescription is transmitted by the practitioner's agent, the transmission shall include the name and title of the individual who transmitted the prescription. The means of transmission shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription.

ITEM 10. Amend rule 657—21.16(124,155A), introductory paragraph, as follows:

657—21.16(124,155A) Facsimile transmission of Schedule II controlled substances—hospice patients. A prescription for a Schedule II controlled substance for a patient enrolled in a hospice care program licensed pursuant to Iowa Code chapter 135J or a program certified or paid for by Medicare under Title XVIII may be transmitted via facsimile by the practitioner or the practitioner's agent to the dispensing pharmacy. If the prescription is transmitted by the practitioner's agent, the transmission shall include the name and title of the individual who transmitted the prescription. The means of transmission shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription.