

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 8, “Universal Practice Standards,” Iowa Administrative Code.

The amendments add pharmacy technicians, pharmacy support persons, and pharmacist-interns to those regulated individuals subject to activities identified as unethical conduct and prohibit any purchasing pharmacy or pharmacist from engaging in any activity or agreeing to any provision in a transaction for the sale or transfer of prescription records that would prevent or prohibit prior patient notification of a pending transfer of the patient’s records. New paragraph 8.16(3)“e” provides that a closing pharmacy may transfer prescription and patient records to a pharmacy that agrees to act as the custodian of the transferred records and that is held to the same confidentiality standards as the originating pharmacy. Amendments to subrule 8.35(6) add catchwords to identify the paragraphs and clarify the applicable rule provisions in the event of a change of owner of a pharmacy.

The amendments to subrule 8.35(7) relate to the responsibilities of the pharmacies when a pharmacy closes. Those responsibilities include: notifications by the closing pharmacy to the Board and the federal Drug Enforcement Administration (DEA) at least 14 days prior to the pharmacy closing and the content of those notifications; notification to the pharmacist in charge of the closing pharmacy at least 21 days prior to the pharmacy closing and including the pharmacist in charge in the notification and closing processes; notification to patients of the closing pharmacy at least 14 days prior to the date of closing, including in such notification information regarding a patient’s right to transfer the patient’s records to a pharmacy of the patient’s choosing, and addressing direct communication to patients and the posting of signs or other public notices; notification to the pharmacist in charge of the receiving pharmacy at least 14 days prior to the pharmacy closing and restricting the receiving pharmacy from contacting patients prior to the transfer of patient records and the closure of the closing pharmacy; and requiring cancellation or revocation of all authorizations to utilize the DEA’s online controlled substances ordering system (CSOS) on behalf of the closing pharmacy. The amendments also require that the closing pharmacy ensure the transfer of all patient records to a pharmacy that is held to the same standards of confidentiality as the closing pharmacy and that agrees to act as custodian for the closing pharmacy’s records for the retention periods required under federal and state laws, rules, and regulations.

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

Notice of Intended Action was published in the December 29, 2010, Iowa Administrative Bulletin as **ARC 9295B**. The Board received numerous written comments regarding the proposed amendments. A majority of the comments, both in support and opposition, related to the extended periods of the various advance notices required by the amendments. A few commenters objected to the requirement that the pharmacists in charge of both the closing and purchasing pharmacy be notified in advance of the transaction, and one commenter objected to Board review of the terms of the sales contract prior to the effective date of the sale.

The adopted amendments differ from those published under Notice.

In paragraph 8.35(7)“a,” the required prior notification to the pharmacist in charge of the closing pharmacy has been changed from 60 days prior to the closing to 21 days prior to the closing and the following sentence has been added: “The owner of the closing pharmacy may direct the pharmacist in charge to maintain information regarding the pending closure of the pharmacy confidential until public notifications are required 14 days prior to the pharmacy closing.”

The notifications to the Board and the DEA required in paragraph 8.35(7)“b” and the notification to patients required in paragraph 8.35(7)“d” have been changed from four weeks to 14 days prior to the pharmacy closing.

Paragraph 8.35(7)“c” has been changed to eliminate the requirement that a copy of the sale or purchase agreement be submitted to the Board with the prior notification and provides that such copy shall be submitted to the Board upon request of the Board.

The term “facilitate” in the first sentence of subparagraph 8.35(7)“d”(1) has been changed to “authorize.” Subparagraph 8.35(7)“d”(1) has also been amended by adding the following sentence: “Written notification shall also remind patients participating in a program or agreement that restricts the patient’s pharmacy services to the closing pharmacy that the patient must contact the program or the party to the agreement to arrange for a change of pharmacy to the purchasing pharmacy or another pharmacy of the patient’s choosing.”

Finally, the name of the DEA’s online ordering system has been corrected in paragraph 8.35(7)“g,” and a cross reference has been corrected in paragraph 8.35(7)“h.”

The amendments were approved during the April 26, 2011, meeting of the Board of Pharmacy.

These amendments will become effective on July 6, 2011.

These amendments are intended to implement Iowa Code sections 147.55 and 155A.13.

The following amendments are adopted.

ITEM 1. Amend rule 657—8.11(147,155A) as follows:

657—8.11(147,155A) Unethical conduct or practice. The provisions of this rule apply to licensed pharmacies, licensed pharmacists, registered pharmacy technicians, registered pharmacy support persons, and registered pharmacist-interns.

8.11(1) *Misrepresentative deeds.* A pharmacist, technician, support person, or pharmacist-intern shall not make any statement intended to deceive, misrepresent or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

8.11(2) *Undue influence.*

a. No change.

~~*b.* The prohibition in paragraph “a” shall not apply until April 23, 2006, to a pharmacist who is working at a prescriber-owned pharmacy location licensed as of April 23, 1981.~~

e. b. A prescriber may employ a pharmacist to provide nondispensing, drug information, or other cognitive services.

8.11(3) No change.

8.11(4) *Nonconformance with law.* A pharmacist, technician, support person, or pharmacist-intern shall not knowingly serve in a pharmacy which is not operated in conformance with law, or which engages in any practice which if engaged in by a pharmacist would be unethical conduct.

8.11(5) *Freedom of choice/solicitation/kickbacks/fee-splitting and imprinted prescription blanks or forms.* A pharmacist or pharmacy shall not enter into any agreement which negates a patient’s freedom of choice of pharmacy services. A purchasing pharmacist or pharmacy shall not engage in any activity or include in any agreement with a selling pharmacist or pharmacy any provision that would prevent or prohibit the prior notifications required in subrule 8.35(7). A pharmacist or pharmacy shall not participate in prohibited agreements with any person in exchange for recommending, promoting, accepting, or promising to accept the professional pharmaceutical services of any pharmacist or pharmacy. “Person” includes an individual, corporation, partnership, association, firm, or other entity. “Prohibited agreements” includes an agreement or arrangement that provides premiums, “kickbacks,” fee-splitting, or special charges as compensation or inducement for placement of business or solicitation of patronage with any pharmacist or pharmacy. “Kickbacks” includes, but is not limited to, the provision of medication carts, facsimile machines, any other equipment, or preprinted forms or supplies for the exclusive use of a facility or practitioner at no charge or billed below reasonable market rate. A pharmacist shall not provide, cause to be provided, or offer to provide to any person authorized to prescribe prescription blanks or forms bearing the pharmacist’s or pharmacy’s name, address, or other means of identification, except that a hospital may make available to hospital staff prescribers, emergency department prescribers, and prescribers granted hospital privileges for the prescribers’ use

during practice at or in the hospital generic prescription blanks or forms bearing the name, address, or telephone number of the hospital pharmacy.

8.11(6) to 8.11(8) No change.

ITEM 2. Amend subrule 8.16(3) as follows:

8.16(3) Exceptions. Nothing in this rule shall prohibit pharmacists from releasing confidential patient information as follows:

a. Transferring a prescription to another pharmacy upon the request of the patient or the patient's authorized representative.

b. Providing a copy of a nonrefillable prescription to the person for whom the prescription was issued which is clearly marked as a copy and not to be filled.

c. Providing drug therapy information to physicians or other authorized prescribers for their patients.

d. Disclosing information necessary for the processing of claims for payment of health care operations or services.

e. Transferring, subject to the provisions of subrule 8.35(7), prescription and patient records of a pharmacy that discontinues operation as a pharmacy to another licensed pharmacy that is held to the same standards of confidentiality and that agrees to act as custodian of the transferred records.

ITEM 3. Amend subrule 8.35(6) as follows:

8.35(6) Pharmacy license changes. When a pharmacy changes its name, location, ownership, or pharmacist in charge, a new pharmacy license application with a license fee as provided in subrule 8.35(4) shall be submitted to the board office. Upon receipt of the fee and properly completed application, the board will issue a new pharmacy license certificate. The old license certificate shall be returned to the board office within ten days of the change of name, location, ownership, or pharmacist in charge.

a. Location. A change of pharmacy location in Iowa shall require an on-site inspection of the new location as provided in subrule 8.35(5) if the new location was not a licensed pharmacy immediately prior to the relocation.

b. Ownership. A change of ownership of a currently licensed Iowa pharmacy, or a change of pharmacy location to another existing Iowa pharmacy location, shall not require on-site inspection pursuant to subrule 8.35(5). A new pharmacy license is required as provided ~~above~~ in this subrule. A change of ownership effectively consists of a closing pharmacy, which is subject to the requirements for a closing pharmacy, and of a new pharmacy, which is subject to the requirements of a new pharmacy, with the possible exception of the on-site inspection as provided by this paragraph. In those cases in which the pharmacy is owned by a corporation, the sale or transfer of all stock of the corporation does not constitute a change of ownership provided the corporation that owns the pharmacy continues to exist and continues to own the pharmacy following the stock sale or transfer.

c. Pharmacist in charge. A change of pharmacist in charge shall require completion and submission of the application and fee for new pharmacy license.

(1) If a permanent pharmacist in charge has not been identified by the time of the vacancy, a temporary pharmacist in charge shall be identified. Written notification identifying the temporary pharmacist in charge, signed by the pharmacy owner or corporate officer and the temporary pharmacist in charge, shall be submitted to the board within 10 days following the vacancy.

(2) Within 90 days following the vacancy, a permanent pharmacist in charge shall be identified, and an application for pharmacy license, including the license fee as provided in subrule 8.35(4), shall be submitted to the board office.

ITEM 4. Amend subrule 8.35(7) as follows:

8.35(7) Pharmacy closing Closing pharmacy. ~~At least two weeks prior to the closing of a pharmacy, a written notice shall be sent to the board and to the Drug Enforcement Administration (DEA) notifying those agencies of the intent to discontinue business or sell the pharmacy including the anticipated date of sale or closing.~~ A closing pharmacy shall ensure that all patient and prescription records are transferred to another pharmacy that is held to the same standards of confidentiality as the closing pharmacy and that agrees to act as custodian of the records for the appropriate retention period for each record type as

required by federal or state laws, rules, or regulations. A pharmacy shall not execute a sale or closing of a pharmacy unless there exists an adequate period of time prior to the pharmacy closing for delivery of the notifications to the pharmacist in charge, the board, the Drug Enforcement Administration (DEA), and pharmacy patients as required by this subrule. However, the provisions of this subrule regarding prior notifications to the board, the DEA, and patients shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster.

a. Pharmacist in charge notification. At the first indication of a pending sale or at the commencement of negotiations regarding the sale or purchase of a pharmacy but not less than 21 days prior to the effective date of the sale of a pharmacy, the pharmacist in charge of the closing pharmacy, if that individual is not an owner of the closing pharmacy, shall be notified of the proposed sale. The owner of the closing pharmacy may direct the pharmacist in charge to maintain information regarding the pending closure of the pharmacy confidential until public notifications are required 14 days prior to the pharmacy closing. The pharmacist in charge of the closing pharmacy shall provide input and direction to the pharmacy owner regarding the responsibilities of the closing pharmacy, including the notifications, deadlines, and time lines established by this subrule. The pharmacist in charge of the closing pharmacy shall prepare patient notifications pursuant to paragraph 8.35(7) “d.” At least 14 days prior to the effective date of the sale of a pharmacy, the pharmacist in charge of the purchasing or receiving pharmacy, if that individual is not an owner of the pharmacy, shall be notified of the pending transaction.

a. b. Board and DEA notifications. ~~Prior notification~~ At least 14 days prior to the closing of a pharmacy, including a closing by sale of a pharmacy, a written notice shall be sent to the board and to the Drug Enforcement Administration (DEA) notifying those agencies of the intent to discontinue business or to sell the pharmacy and including the anticipated date of closing. These prior notifications shall include the name, address, DEA registration number, Iowa pharmacy license number, and Iowa controlled substances Act (CSA) registration number of the closing pharmacy and of the pharmacy to which prescription drugs will be transferred. ~~Notification~~ Notifications shall also include the name, address, DEA registration number, Iowa pharmacy license number, and CSA registration number of the location at which prescription files, patient profiles, and controlled substance receipt and disbursement records will be maintained.

b. c. Terms of sale or purchase. ~~Pharmacy patients with active prescriptions on file with a pharmacy that intends to close permanently shall be notified by that pharmacy, via direct mail or public notice at least two weeks prior to the closure of the pharmacy, that each patient has the right to transfer the patient’s active prescriptions to a pharmacy of the patient’s choosing. This paragraph shall not apply in the case of an emergency or unforeseeable closure including, but not limited to, emergency board action, foreclosure, fire, or natural disaster. If the closing is due to the sale of the pharmacy, a copy of the sale or purchase agreement, not including information regarding the monetary terms of the transaction, shall be submitted to the board upon the request of the board. The agreement shall include a written assurance from the closing pharmacy to the purchasing pharmacy that the closing pharmacy has given or will be giving notice to its patients as required by this subrule.~~

d. Patient notification. At least 14 days prior to closing, a closing pharmacy shall make a reasonable effort to notify all patients who had a prescription filled by the closing pharmacy within the last 18 months that the pharmacy intends to close, including the anticipated closing date.

(1) Written notification shall identify the pharmacy that will be receiving the patient’s prescriptions and records, shall include information on the rights of the patient to transfer current prescriptions and patient records to a pharmacy of the patient’s choosing including information on how such transfer may be accomplished, and shall include a form that may be completed by the patient and submitted to the closing pharmacy to authorize transfer of the patient’s prescriptions and records to a pharmacy of the patient’s choosing. Written notification shall also remind patients participating in a program or agreement that restricts the patient’s pharmacy services to the closing pharmacy that the patient must contact the program or the party to the agreement to arrange for a change of pharmacy to the purchasing pharmacy or another pharmacy of the patient’s choosing.

(2) Written notification shall be delivered to each patient at the patient's last address on file with the closing pharmacy by direct mail or personal delivery and also by public notice. Public notice refers to the display, in a location and manner clearly visible to patients, of signs in pharmacy pickup locations including drive-through prescription pickup lanes, on pharmacy or retail store entry and exit doors, or at pharmacy prescription counters. In addition, notice may be posted on the pharmacy's Web site, displayed on a marquee or electronic sign, communicated via automated message on the pharmacy's telephone system, or published in one or more local newspapers or area shopper publications.

e. Patient communication by receiving pharmacy. A pharmacy receiving the patient records of another pharmacy shall not contact the patients of the closing pharmacy until after the transfer of those patient records from the closing pharmacy to the receiving pharmacy and after the closure of the closing pharmacy. The receiving pharmacy shall post or publish notice to patients of their right to transfer current prescriptions and patient records to a pharmacy of the patient's choosing, including information on how such transfer can be accomplished. A notice posted at the receiving or purchasing pharmacy shall be maintained for a minimum 90 days following the transfer of patient records from the closing pharmacy.

e.f. Prescription drug inventory. A complete inventory of all prescription drugs being transferred shall be taken as of the close of business. The inventory shall serve as the ending inventory for the closing pharmacy as well as a record of additional or starting inventory for the pharmacy to which the drugs are transferred. A copy of the inventory shall be included in the records of each licensee.

(1) to (5) No change.

d. g. Surrender of certificates and forms. The pharmacy license certificate and CSA registration certificate of the closing ~~or selling~~ pharmacy shall be returned to the board office within ten days of closing ~~or sale~~. The DEA registration certificate and all unused DEA Forms 222 shall be returned to the DEA within ten days of closing. All authorizations to utilize the DEA's online controlled substances ordering system (CSOS) and all digital certificates issued for the purpose of ordering controlled substances for the closing pharmacy shall be canceled or revoked within ten days of closing.

e. h. Signs at closed pharmacy location. A location that no longer houses a licensed pharmacy shall not display any sign, placard, or other notification, visible to the public, which identifies the location as a pharmacy. A sign or other public notification that cannot feasibly be removed shall be covered so as to conceal the identification as a pharmacy. Nothing in this paragraph shall prohibit the display of a public notice to patients, as required in paragraph 8.35(7) "d," for a reasonable period not to exceed six months following the pharmacy closing.

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