657—8.35 (155A) Pharmacy license. A pharmacy license issued by the board is required for all sites where prescription drugs are offered for sale or dispensed under the supervision of a pharmacist. A pharmacy license issued by the board is also required for all sites where drug information or other cognitive pharmacy services, including but not limited to drug use review and patient counseling, are provided by a pharmacist. The board may issue any of the following types of pharmacy licenses: a general pharmacy license, a hospital pharmacy license, a special or limited use pharmacy license, or a nonresident pharmacy license. Nonresident pharmacy license applicants shall comply with board rules regarding nonresident pharmacy practice except when specific exemptions have been granted. Applicants for general or hospital pharmacy practice shall comply with board rules regarding general or hospital pharmacy practice except when specific exemptions have been granted. Any pharmacy located within Iowa that dispenses controlled substances must also register pursuant to 657—Chapter 10.

8.35(1) *Exemptions.* Applicants who are granted exemptions shall be issued a "general pharmacy license with exemption," a "hospital pharmacy license with exemption," a "nonresident pharmacy license with exemption," or a "limited use pharmacy license with exemption" and shall comply with the provisions set forth by that exemption. A written petition for exemption from certain licensure requirements shall be submitted pursuant to the procedures and requirements of 657—Chapter 34 and will be determined on a case-by-case basis.

8.35(2) *Limited use pharmacy license.* Limited use pharmacy license may be issued for nuclear pharmacy practice, correctional facility pharmacy practice, and veterinary pharmacy practice. Applications for limited use pharmacy license for these and other limited use practice settings shall be determined on a case-by-case basis.

8.35(3) *Application form.* Application for licensure and license renewal shall be on forms provided by the board. The application for a pharmacy license shall require an indication of the pharmacy ownership classification. If the owner is a sole proprietorship (100 percent ownership), the name and address of the owner shall be indicated. If the owner is a partnership or limited partnership, the names and addresses of all partners shall be listed or attached. If the owner is a corporation, the names and addresses of the officers and directors of the corporation shall be listed or attached. Any other pharmacy ownership classification shall be further identified and explained on the application. The application form shall require the name, signature, and license number of the pharmacist in charge. The names and license numbers of all pharmacists engaged in practice in the pharmacy, the names and registration numbers of all pharmacy technicians and pharmacy support persons working in the pharmacy, and the average number of hours worked by each pharmacist, pharmacy technician, and pharmacy support person shall be listed or attached. Additional information may be required of specific types of pharmacy license applicants. The application shall be signed by the pharmacy owner or the owner's, partnership's, or corporation's authorized representative.

8.35(4) *License expiration and renewal.* General pharmacy licenses, hospital pharmacy licenses, special or limited use pharmacy licenses, and nonresident pharmacy licenses shall be renewed before January 1 of each year. The fee for a new or renewal license shall be $135.

a. Late payment penalty. Failure to renew the pharmacy license before January 1 following expiration shall require payment of the renewal fee and a penalty fee of $135. Failure to renew the license before February 1 following expiration shall require payment of the renewal fee and a penalty fee of $225. Failure to renew the license before March 1 following expiration shall require payment of the renewal fee and a penalty fee of $315. Failure to renew the license before April 1 following expiration shall require payment of the renewal fee and a penalty fee of $405 and may require an appearance before the board. In no event shall the combined renewal fee and penalty fee for late renewal of a pharmacy license exceed $540.

b. Delinquent license. If a license is not renewed before its expiration date, the license is delinquent and the licensee may not operate or provide pharmacy services to patients in the state of Iowa until the licensee renews the delinquent license. A pharmacy that continues to operate in Iowa without a current license may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.1(4).

8.35(5) *Inspection of new pharmacy location.* If the new pharmacy location within Iowa was not a licensed pharmacy immediately prior to the proposed opening of the new pharmacy, the pharmacy location shall require an on-site inspection by a pharmacy board inspector prior to the issuance of the pharmacy license. The purpose of the inspection is to determine compliance with requirements pertaining to space, library, equipment, security, temperature control, and drug storage safeguards. Inspection may be scheduled anytime following submission of necessary license and registration applications and prior to opening for business as a pharmacy. Prescription drugs, including controlled substances, may not be delivered to a new pharmacy location prior to satisfactory completion of the opening inspection.

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 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 a 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 shall be submitted to the board by the pharmacy owner or the pharmacy owner's authorized representative and by the temporary pharmacist in charge 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.

8.35(7) *Closing pharmacy.* 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 least 40 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 30 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 30 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.

b. Board and DEA notifications. At least 30 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. 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.

c. Terms of sale or purchase. 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 30 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. The notification shall advise patients that if they have any questions regarding their prescriptions and records that they may contact the closing pharmacy. If the closing pharmacy receives no contact from the patient within the 30-day notification period prior to the pharmacy closing, all patient information will be transferred to the receiving pharmacy. The notification shall also advise patients that after the date of closing patients may contact the pharmacy to which the prescriptions and records have been transferred.

(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.

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) DEA Form 222 is required for transfer of Schedule II controlled substances.

(2) The inventory of controlled substances shall be completed pursuant to the requirements in 657—10.35(124,155A).

(3) The inventory of all noncontrolled prescription drugs may be estimated.

(4) The inventory shall include the name, strength, dosage form, and quantity of all prescription drugs transferred.

(5) Controlled substances requiring destruction or other disposal shall be transferred in the same manner as all other drugs. The new owner is responsible for the disposal of these substances as provided in rule 657—10.18(124).

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.

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.

8.35(8) *Failure to complete licensure.* An application for a pharmacy license, including an application for registration pursuant to 657—Chapter 10, if applicable, will become null and void if the applicant fails to complete the licensure process within six months of receipt by the board of the required applications. The licensure process shall be complete upon the pharmacy's opening for business at the licensed location following an inspection rated as satisfactory by an agent of the board if such an inspection is required pursuant to this rule. When an applicant fails to timely complete the licensure process, fees submitted with applications will not be transferred or refunded.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9526B**, IAB 6/1/11, effective 7/6/11 (See Delay note at end of chapter); **ARC 9693B**, IAB 9/7/11, effective 8/11/11; **ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 1962C**, IAB 4/15/15, effective 5/20/15]