PHARMACY BOARD[657]

[Prior to 2/10/88, see Pharmacy Examiners, Board of [620], renamed Pharmacy Examiners Board[657] under the "umbrella" of Public Health Department by 1986 Iowa Acts, ch 1245; renamed by 2007 Iowa Acts, Senate File 74]

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CHAPTER 1
PURPOSE AND ORGANIZATION

[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 9]

657—1.1(17A) Board mission. The board of pharmacy promotes, preserves, and protects the public health, safety, and welfare by fostering the provision of pharmaceutical care to all Iowans through the effective regulation of the practice of pharmacy, the operation of pharmacies, the appropriate utilization of pharmacy technicians, the distribution of prescription drugs and devices, and the education and training of pharmacists.

657—1.2(17A,147,272C) Description and organization of board. The board is comprised of five pharmacist members and two representatives of the general public, all appointed by the governor. An administrative staff headed by a board-appointed executive director assists board members.

The board's authority for regulating the practice of pharmacy and the legal distribution and dispensing of prescription drugs and devices and of precursor substances in the state of Iowa is found in Iowa Code chapters 124, 124A, 124B, 126, 147, 155A, 205, and 272C.

657—1.3(17A,272C) Responsibilities. The responsibilities of the board include but are not limited to:

1. Licensing of qualified applicants for the practice of pharmacy, by examination, renewal, and reciprocity under the provisions of Iowa Code chapters 147 and 155A.
2. Administering a continuing education program to ensure continued competency of individuals licensed by the board to practice pharmacy. Authority for this function comes from Iowa Code chapter 272C.
3. Regulating the legal distribution of prescription drugs through the licensing of pharmacies and wholesalers under the authority of Iowa Code chapter 155A.
4. Regulating the legal distribution of controlled substances through the registration of authorized persons and entities engaged in the manufacture and distribution of controlled substances throughout the state under the authority of Iowa Code chapter 124.
5. Registering pharmacist-interns and administering an internship program to prepare individuals for the practice of pharmacy pursuant to the authority of Iowa Code chapter 155A.
6. Registering pharmacy technicians assisting in the technical functions of the practice of pharmacy pursuant to the authority of Iowa Code chapter 155A.
7. Performing compliance investigations and audits of all persons or entities registered pursuant to Iowa Code chapter 124 and compliance inspections and investigations of any persons or entities licensed or registered pursuant to Iowa Code chapter 155A. These investigations and audits are conducted to ensure accountability for all controlled substances and to ensure compliance with laws regulating the practice of pharmacy and the distribution of prescription drugs and devices in Iowa.
8. Regulating the legal distribution of precursor substances through the issuance of permits to vendors and recipients of precursor substances throughout the state under the authority of Iowa Code chapter 124B.
9. Instituting disciplinary actions, hearing contested cases, issuing decisions and orders, and enforcing the terms of disciplinary orders filed against licensees, registrants, or permit holders for grounds provided in Iowa Code sections 124.303, 124.304, 124B.12, 147.55, 155A.6, 155A.12, 155A.13A, 155A.15, and 155A.17, as appropriate.

657—1.4(17A,272C) Submission of complaints and requests. Members of the general public may obtain information or submit requests or complaints relative to the practice of pharmacy, continuing education for pharmacists, the legal distribution and dispensing of prescription drugs, or any other matters relating to the function and authority of the board. Correspondence should be submitted to the Executive Director, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Communication may also be submitted via the board's Web site at www.state.ia.us/ibpe.

657—1.5(17A,21) Meetings. All meetings of the board shall be open and public, and all members of the public shall be permitted to attend any meeting unless Iowa Code section 21.5 or another provision of law authorizes a closed session. Closed session shall only be by affirmative public vote of either two-thirds of the members of the board or all of the members present at the meeting.

1.5(1) *Where held.* Meetings of the board shall be held in Des Moines, Iowa, except as designated otherwise by the chairperson.

1.5(2) *Meeting schedule and public notice.* The board shall set the dates of its meetings at the first meeting following May 1 of each fiscal year. Notices of meetings shall be routinely posted in the space set aside for that purpose in the office of the board and on the board's Web site at www.state.ia.us/ibpe. Members of the general public may obtain the dates, times, and locations of board meetings by submitting a request to the Executive Director, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, or by accessing the board's Web site.

1.5(3) *Special meetings.* Special meetings of the board may be called by the chairperson or upon written request of four of its members.

a. The reason for calling a special meeting shall be recorded in the minutes.

b. Special meetings shall be open to the public except as otherwise provided by statute.

1.5(4) *Minutes of meetings.* The executive secretary shall keep a record of all minutes of the board, and these minutes, except as otherwise provided by statute, shall be open to the public for inspection.

1.5(5) *Quorum.* A majority of the members of the board shall constitute a quorum.

Rules 657—1.1(17A) through 657—1.5(17A,21) are intended to implement Iowa Code sections 17A.3, 21.3 through 21.5, 124.301, 147.14, 147.76, 155A.2, 272C.3, and 272C.4.

657—1.6(124,147,155A) Fee for returned check. A fee of $20 may be charged for a check returned for any reason. If a license, registration, or permit has been issued by the board office based on a check for the payment of fees and the check is later returned by the bank, the board shall request payment by certified check, cashier's check, or money order. If the fees, including the fee for a returned check, are not paid within 15 calendar days of notification of the returned check, the license, registration, or permit is no longer in effect and the status reverts to what it would have been had the license, registration, or permit not been issued. Late payment penalties will be assessed, as provided in board rules, for subsequent requests to renew or reissue the license, registration, or permit.

657—1.7(124,124B,147,155A) Overpayment of fees. "Overpayment" refers to the payment of any license, registration, permit, or service fee in excess of the required amount of the fee. Overpayment of $10 or less received by the board shall not be refunded.

These rules are intended to implement Iowa Code sections 124.301, 124B.11, 147.96, 155A.6, 155A.11, 155A.13, 155A.13A, 155A.14, and 155A.17.

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◊ Two or more ARCs

CHAPTER 2
PHARMACIST LICENSES

[Prior to 2/10/88, see Pharmacy Examiners[620] Chs 1, 5]

657—2.1(147,155A) Licensure by examination. The board of pharmacy, in conjunction with the National Association of Boards of Pharmacy (NABP), shall provide for the administration of pharmacist licensure examinations.

2.1(1) *Components.* Applicants shall take and pass the following components: the North American Pharmacist Licensure Examination (NAPLEX); the Multistate Pharmacy Jurisprudence Examination (MPJE), Iowa Edition. A total scaled score of no less than 75 is required to pass each examination.

2.1(2) *Timeliness.* To be eligible for a license by examination, the candidate shall pass all components in Iowa within a period of one year beginning with the date the candidate passed an initial component. A candidate may request waiver or variance from this deadline pursuant to the procedures and requirements of 657—Chapter 34.

657—2.2(155A) Application for examination—requirements. Application for examination shall be on forms provided by the board, and all requested information shall be provided on or with such application. An applicant shall complete the NABP Computerized Examination Registration Form to apply for registration to take the NAPLEX. An applicant shall complete an additional registration form to apply for registration to take the MPJE, Iowa Edition.

2.2(1) *Required information.* The application for examination shall require that the applicant provide, at a minimum, the following: name; address; telephone number; date of birth; social security number; name and location of college of pharmacy and date of graduation; one current photograph of a quality at least similar to a passport photograph; and internship experience. Each applicant shall also declare the following: history of prior pharmacist licensure examinations and record of offenses including but not limited to charges, convictions, and fines which relate to the profession or that may affect the licensee's ability to practice pharmacy.

2.2(2) *Sworn statement.* The application for examination shall be made as a sworn statement before a notary public, and the notary public shall witness the signature of the applicant.

657—2.3(147,155A) Examination fee. The fee for examination shall consist of the biennial license fee, a processing fee, administration fees, and examination registration fees.

2.3(1) *Fees to the board.* The biennial license fee shall be the fee established by rule 2.11(147,155A), including surcharge. The processing fee shall be $80. No refunds of the processing fee shall be made for cancellation or withdrawal of applications. The license fee and processing fee shall be payable to the Iowa Board of Pharmacy and may be remitted in the form of personal check, money order, or certified check. No refund of fees shall be made for failure to complete all licensure requirements within the period specified in subrule 2.1(2).

2.3(2) *Fees to NABP.* The examination registration and administration fees shall be amounts determined by NABP, shall be payable to the National Association of Boards of Pharmacy, and shall be in the form of a certified check or money order. Refunds of fees paid to NABP shall be at the discretion of NABP.

2.3(3) *Submission of forms and fees.* The biennial license fee including surcharge, the processing fee, the administration fees, and the examination registration fees shall accompany the applications and registration forms and shall be submitted to the Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, or as otherwise directed by the board.

657—2.4(155A) Internship requirements. Each applicant shall furnish to the board evidence certifying completion of satisfactory internship experience. The board will not certify an applicant eligible to take any of the examination components prior to receipt of evidence of satisfactory completion of internship experience. Internship experience shall comply with the requirements in 657—Chapter 4. Internship experience completed in compliance with the requirements in 657—Chapter 4 shall be valid for application for licensure in Iowa by examination or score transfer for a period of three years

following graduation from an approved college of pharmacy or as otherwise approved by the board on a case-by-case basis.

657—2.5(155A) College graduate certification. Each applicant shall furnish a certificate from a recognized college of pharmacy stating that the applicant has successfully graduated from a school or college of pharmacy with either a bachelor of science degree in pharmacy or a doctor of pharmacy (Pharm.D.) degree. Certification shall be completed by an individual authorized by the college on a form provided by the board. A recognized college of pharmacy is a United States institution that meets the minimum standards of the American Council on Pharmaceutical Education and appears on its list of accredited colleges of pharmacy published by the council as of July 1 of each year.

657—2.6(147) Reexamination applications and fees. A candidate who fails to pass the NAPLEX once shall be allowed to schedule a time to retake the examination no less than 91 days following administration of the failed examination. A candidate who fails to pass the MPJE, Iowa Edition, once shall be allowed to schedule a time to retake the examination no less than 30 days following administration of the failed examination. A candidate who fails to pass either examination following a second or subsequent examination may petition the board for permission to take the examination again. Determination of a candidate's eligibility to take an examination more than two times shall be at the discretion of the board.

Each applicant for reexamination shall file an application on forms provided by the board. Processing fees of $40 each will be charged to take NAPLEX or MPJE, Iowa Edition, and shall be paid to the board as provided in subrule 2.3(1). In addition, candidates will be required to complete the appropriate examination registration application as provided in rule 2.2(155A) and to pay to NABP the registration and administration fees for each examination as provided in subrule 2.3(2). All applications, registration forms, and fees shall be submitted as provided in subrules 2.3(2) and 2.3(3).

657—2.7(147) Examination results. Examination scores and original license certificates shall be provided to each new licensee as soon after the examinations as possible.

657—2.8(155A) Transfer of examination scores. The board of pharmacy participates in the NAPLEX score transfer program offered by NABP. This program allows candidates for pharmacist licensure to take the standardized NAPLEX in one state and have the score from that examination transferred to other participant states in which the candidate is seeking licensure. MPJE scores cannot be transferred.

2.8(1) *Score transfer application.* The NAPLEX Score Transfer Form must be completed and submitted with the proper fee to NABP prior to, or postmarked no later than, the date on which the candidate takes the NAPLEX. The fee to NABP for score transfer is determined by NABP. Payment shall be made in the form of a money order or certified check payable to the National Association of Boards of Pharmacy. NABP makes no refunds of score transfer fees.

2.8(2) *Requirements and deadline.* Score transfer candidates shall meet the requirements established in rules 2.1(147,155A) through 2.5(155A) within 12 months of the date of transfer. No refund of fees paid to the board will be made for failure to complete all licensure requirements within this one-year period.

2.8(3) *Fees.* In addition to the score transfer fee identified in subrule 2.8(1), fees for licensure pursuant to the NABP score transfer program shall consist of the fees identified in rule 2.3(147,155A) excluding the NAPLEX examination registration and administration fees.

657—2.9(147,155A) Licensure by license transfer/reciprocity. An applicant for license transfer/reciprocity must be a pharmacist licensed by examination in a state or territory of the United States with which Iowa has a reciprocal agreement, and the license by examination must be in good standing at the time of the application. All candidates shall take and pass the MPJE, Iowa Edition, as provided in subrule 2.1(1). Any candidate who fails to pass the examination shall be eligible for reexamination as provided in rule 2.6(147).

2.9(1) *Eligibility.* Each applicant for license transfer to this state who obtains the applicant's original license after January 1, 1980, must have passed the NABP Licensure Examination (NABPLEX), the NAPLEX, or an equivalent examination as determined by NABP.

a. Preliminary application. Each applicant for license transfer/reciprocity to Iowa shall complete and submit to NABP, with the appropriate fee as indicated on the application, the NABP Preliminary Application for Transfer of Pharmaceutic Licensure. Refunds of fees paid to NABP shall be at the discretion of NABP.

b. Foreign pharmacy graduates. If the applicant is a graduate of a school or college of pharmacy located outside the United States that has not been recognized and approved by the board, proof of qualifications shall include certification from the FPGEC pursuant to subrule 2.10(1).

2.9(2) *Application requirements.* Application to the board shall consist of the final application for license transfer prepared by NABP pursuant to the NABP license transfer program. A foreign pharmacy graduate shall submit certification from the FPGEC as provided in subrule 2.10(1). Applications, together with other required information and fees, shall be submitted as provided in subrule 2.3(3).

2.9(3) *MPJE required.* An applicant shall also be required to submit the registration application for MPJE, Iowa Edition, as provided in rule 2.2(155A). The form and fees shall be submitted as provided in subrules 2.3(2) and 2.3(3).

2.9(4) *Fees.* The fee for license transfer shall consist of the biennial license fee established by rule 2.11(147,155A) including surcharge and a processing fee of $100. No refunds of the processing fee shall be made for cancellation or withdrawal of an application. The license fee and processing fee shall be payable to the Iowa Board of Pharmacy and may be remitted in the form of personal check, money order, or certified check.

2.9(5) *Timeliness.* A final application for license transfer is valid for 12 months following the date of issuance by NABP. A candidate for license transfer shall complete, within that one-year period, all licensure requirements established by this rule. No refund of fees will be made for failure to complete all licensure requirements within this one-year period.

657—2.10(155A) Foreign pharmacy graduates.

2.10(1) *Education equivalency.* Any applicant who is a graduate of a school or college of pharmacy located outside the United States that has not been recognized and approved by the board shall be deemed to have satisfied the requirements of Iowa Code section 155A.8, subsection 1, by certification by the Foreign Pharmacy Graduate Examination Committee (FPGEC). Each applicant shall have successfully passed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) given by the FPGEC established by the NABP. The FPGEE is hereby recognized and approved by the board. Each applicant shall also demonstrate proficiency in written English by passing the Test of English as a Foreign Language (TOEFL) and proficiency in spoken English by passing the Test of Spoken English (TSE) or proficiency in basic English language skills by passing the Internet Based TOEFL (TOEFL iBT). The TOEFL, TOEFL iBT, and TSE are hereby recognized and approved by the board. Certification by the FPGEC shall be evidence of the applicant's successfully passing the FPGEE, TSE, and TOEFL, or the FPGEE and TOEFL iBT, and certification is a prerequisite to taking the licensure examinations required in subrule 2.1(1).

2.10(2) *Internship.* A foreign pharmacy graduate applicant shall also be required to obtain internship experience in one or more board-licensed community or hospital pharmacies as provided in rule 657—4.7(155A). Internship requirements shall, in all other aspects, meet the requirements established in 657—Chapter 4.

657—2.11(147,155A) License expiration and renewal. A license to practice pharmacy shall expire on the second thirtieth day of June following the date of issuance of the license, with the exception that a new pharmacist license issued between April 1 and June 29 shall expire on the third thirtieth day of June following the date of issuance. The license renewal certificate shall be issued upon completion of the renewal application and timely payment of a $200 fee plus applicable surcharge pursuant to 657—30.8(155A).

2.11(1) *Late payment penalty.* Failure to renew the license before July 1 following expiration shall require payment of the renewal fee, a penalty fee of $200, and applicable surcharge pursuant to 657—30.8(155A). Failure to renew the license before August 1 following expiration shall require payment of the renewal fee, a penalty fee of $300, and applicable surcharge pursuant to 657—30.8(155A). Failure to renew the license before September 1 following expiration shall require payment of the renewal fee, a penalty fee of $400, and applicable surcharge pursuant to 657—30.8(155A). Failure to renew the license before October 1 following expiration may require an appearance before the board and shall require payment of the renewal fee, a penalty fee of $500, and applicable surcharge pursuant to 657—30.8(155A). In no event shall the combined fee and penalty fee for late renewal of the license exceed $700 plus applicable surcharge pursuant to 657—30.8(155A). The provisions of Iowa Code section 147.11 shall apply to a license that is not renewed within five months of the expiration date.

2.11(2) *Delinquent license.* If a license is not renewed before its expiration date, the license is delinquent and the licensee may not practice pharmacy in the state of Iowa until the licensee reactivates the delinquent license. Reactivation of a delinquent license shall include submission of a completed application and appropriate fees and may include requirements relating to the reactivation of an inactive license pursuant to subrule 2.13(2). A pharmacist who continues to practice pharmacy in Iowa without a current license may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.1(4).

657—2.12(272C) Continuing education requirements.

2.12(1) *Continuing education program attendance.* Continuing education programs that carry the seal of an American Council on Pharmaceutical Education (ACPE) approved provider will automatically qualify for continuing education credit. Program attendance is mandated in order to receive credit unless the program is a correspondence course that ACPE approved.

a. Non-ACPE provider program. A pharmacist requesting individual credit for completing a non-ACPE provider program shall submit a request for approval of the program to the board office no later than the date the program commences. The request shall be made on forms provided by the board office.

b. Exemption for health-related graduate studies. A pharmacist who is continuing formal education in health-related graduate programs may be exempted from meeting the continuing education requirements during the period of such enrollment. An applicant for this exemption shall petition the board, as soon as possible following enrollment in the qualifying graduate program, on forms provided by the board office.

2.12(2) *Continuing education unit required.* The nationally accepted measurement of continuing education is referred to as CEU (continuing education unit), and the board of pharmacy employs that measurement. Ten contact hours of approved continuing education are equivalent to one CEU. The board of pharmacy will require 3.0 CEUs each renewal period. For purposes of this rule, "renewal period" means the 27-month period commencing April 1 prior to the previous license expiration and ending June 30, the date of current license expiration. A pharmacist who fails to complete the required CEUs within the renewal period shall be required to complete one and one-half times the number of delinquent CEUs prior to reactivation of the license. CEUs that are used to satisfy the continuing education requirement for one renewal period shall not be used to satisfy the requirement for a subsequent renewal period.

2.12(3) *Continuing education program attendance certificate.*

a. An approved provider will be required to make available to an individual pharmacist a certificate that indicates successful completion and participation in a continuing education program. The certificate will carry the following information:

(1) Pharmacist's full name.
(2) Pharmacist's license number.
(3) Number of contact hours for program attended.
(4) Date and place of continuing education program.
(5) Name of program provider.

(6) An indicator of the type or category of continuing education program completed.

b. A pharmacist must retain certificates in the pharmacist's personal files for four years.

2.12(4) *Continuing education program topics.* Each pharmacist is required to obtain a minimum of 50 percent of the pharmacist's required 3.0 CEUs in ACPE-approved courses dealing with drug therapy. Programs qualifying for the drug therapy course requirement will include the ACPE topic designator "01" in the last two digits of the program number.

2.12(5) *New license holders licensed by examination.* After the initial license is issued by examination, the new license holder is exempt from meeting continuing education requirements for the first license renewal. However, if the licensee qualifies as a mandatory abuse reporter, the licensee shall not be exempt from mandatory training for identifying and reporting abuse pursuant to rule 2.16(235B,272C). Regardless of when the license is first issued, the new license holder will be required to obtain, prior to the second renewal, 30 contact hours (3.0 CEUs) of continuing education pursuant to subrules 2.12(1) through 2.12(4).

2.12(6) *New license holders licensed by license transfer/reciprocity.* After the initial license is issued by license transfer, the new license holder will be required to obtain, prior to the first license renewal, 30 contact hours (3.0 CEUs) of continuing education credits pursuant to subrules 2.12(1) through 2.12(4).

2.12(7) *Reporting continuing education credits.*

a. A pharmacist shall submit on or with the renewal application form documentation that the continuing education requirements have been met. Documentation shall be in a format that includes the following:

(1) The total number of credits accumulated for the renewal period;

(2) The individual programs attended;

(3) The dates of participation;

(4) The credits awarded for each course;

(5) The name of the provider of each course; and

(6) Identification of the programs completed to comply with the drug therapy course requirements in subrule 2.12(4).

b. The board may require a pharmacist to submit the program attendance certificates that document completion of the programs included with or on the renewal application.

c. Failure to receive the renewal application shall not relieve the pharmacist of the responsibility of meeting continuing education requirements.

2.12(8) *Relicensure examination.* Nothing in these rules precludes the board from requiring an applicant for renewal to submit to a relicensure examination.

2.12(9) *Physical disability or illness.* The board may, in individual cases involving physical disability or illness, grant waivers of the minimum continuing education requirements or extensions of time within which to fulfill the same or make the required reports. No waiver or extension of time shall be granted unless written application is made and signed by the licensee and the licensee's physician. The board may grant waivers of the minimum continuing education requirements for physical disability or illness for any period of time not to exceed one renewal period. In the event that the physical disability or illness upon which a waiver has been granted continues beyond the period of the waiver, the licensee must reapply for an extension of the waiver. The board may, as a condition of any waiver granted, require the licensee to make up all or any portion of the waived continuing education requirements by any method prescribed by the board.

657—2.13(272C) Active and inactive license status.

2.13(1) *Active license.* Active license status applies to a pharmacist who has submitted the renewal application and fee and has met Iowa requirements for continuing education. Active license status also applies to a pharmacist who has submitted the renewal application and fee and who is a resident of another state, is licensed to practice pharmacy in that state, and has met the continuing education requirements of that state. A pharmacist who meets the continuing education requirements of another state shall provide documentation on the renewal application of the pharmacist's license status in that state. An

Iowa licensee actively practicing in a state that does not require continuing education for license renewal shall be required to meet Iowa continuing education requirements.

2.13(2) *Inactive license.* Failure of a pharmacist to comply with the continuing education requirements during the renewal period will result in the issuance of a renewal card marked "inactive" upon submission of the renewal application and fee. Reactivation of an inactive pharmacist license shall be accomplished by the appropriate method described below. Internship, in each instance where internship is mentioned below, shall be in a pharmacy approved by the board. The pharmacist will be issued an intern registration certificate.

a. An inactive pharmacist who wishes to become active and who has been actively practicing pharmacy during the last five years in any state or states which required continuing education during that five-year period shall submit proof of continued licensure in good standing in the state or states of such practice.

b. An inactive pharmacist who wishes to become active and who has been actively practicing pharmacy during the last five years in a state which does not require continuing education shall submit proof of continued licensure in good standing in the state or states of such practice. The pharmacist shall also complete one of the following options:

(1) Take and successfully pass the MPJE, Iowa Edition, as provided in subrule 2.1(1);

(2) Complete 160 hours of internship for each year the pharmacist was on inactive status (not to exceed 1,000 hours); or

(3) Obtain one and one-half times the number of continuing education credits required under 2.12(2) for each renewal period the pharmacist was inactive.

c. An inactive pharmacist who wishes to become active and who has not been actively practicing pharmacy during the past five years, and whose license has been inactive for not more than five years, shall complete one of the following options:

(1) Successfully pass all components of the licensure examination as required in rule 2.1(147,155A);

(2) Complete 160 hours of internship for each year the pharmacist was on inactive status; or

(3) Obtain one and one-half times the number of continuing education credits required under 2.12(2) for each renewal period the pharmacist was inactive.

d. An inactive pharmacist who wishes to become active and who has not been actively practicing pharmacy for more than five years shall petition the board for reactivation of the license to practice pharmacy under one or more of the following options:

(1) Successfully pass all components of the licensure examination as required in rule 2.1(147,155A);

(2) Complete 160 hours internship for each year the pharmacist was on inactive status (not to exceed 1,000 hours); or

(3) Obtain one and one-half times the number of continuing education credits required under 2.12(2) for each renewal period the pharmacist was inactive.

657—2.14(155A) Fees for additional license certificates. Only original license certificates issued by the board of pharmacy for licensed pharmacists are valid. Additional original license certificates for licensed pharmacists may be obtained from the board of pharmacy for a prepaid fee of $20 each. The fee shall be considered a repayment receipt as defined in Iowa Code section 8.2.

657—2.15(155A) Notifications to the board. A pharmacist shall report to the board within ten days a change of the pharmacist's name, address, or pharmacy employment.

657—2.16(235B,272C) Mandatory training for identifying and reporting abuse. "Mandatory training for identifying and reporting abuse" means training on identifying and reporting child abuse or dependent adult abuse required of a pharmacist who qualifies as a mandatory abuse reporter under Iowa Code section 232.69 or 235B.16. A licensed pharmacist shall be responsible for determining whether

or not, by virtue of the pharmacist's practice or employment, the pharmacist qualifies as a mandatory abuse reporter under either or both of these sections.

2.16(1) *Training required.* A licensed pharmacist who qualifies as a mandatory abuse reporter shall have completed approved abuse education training as follows.

a. Mandatory reporter of child abuse. A pharmacist who qualifies as a mandatory reporter of child abuse shall have completed two hours of training in child abuse identification and reporting within the previous five years.

b. Mandatory reporter of dependent adult abuse. A pharmacist who qualifies as a mandatory reporter of dependent adult abuse shall have completed two hours of training in dependent adult abuse identification and reporting within the previous five years.

c. Mandatory reporter of child abuse and dependent adult abuse. A pharmacist who qualifies as a mandatory reporter of child abuse and dependent adult abuse may complete separate courses pursuant to paragraphs *"a"* and *"b"* or may complete, within the previous five years, one combined two-hour course that includes curricula for identifying and reporting child abuse and dependent adult abuse.

2.16(2) *Persons exempt from training requirements.* The requirements of this rule shall not apply to a pharmacist during periods that the pharmacist serves honorably on active duty in the military or during periods that the pharmacist resides outside Iowa and does not practice pharmacy in Iowa.

2.16(3) *Mandatory training records.* A pharmacist subject to the requirements of this rule shall maintain documentation of completion of the mandatory training for identifying and reporting abuse, including dates, subjects, duration of programs, and proof of participation, for five years following the date of the training. The board may audit this information at any time within the five-year period.

2.16(4) *Approved programs.* "Approved abuse education training" means a training program using a curriculum approved by the abuse education review panel of the Iowa department of public health.

These rules are intended to implement Iowa Code sections 147.10, 147.36, 147.94, 147.96, 155A.8, 155A.9, 155A.11, 155A.39, and 272C.2.

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CHAPTER 3
PHARMACY TECHNICIANS
[Prior to 9/4/02, see 657—Ch 22]

657—3.1(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Cashier" means a person whose duties within the pharmacy are limited to accessing finished, packaged prescription orders and processing payments for and delivering such orders to the patient or the patient's representative.

"Certified pharmacy technician" or *"certified technician"* means an individual who holds a valid current national certification and who has registered with the board as a certified pharmacy technician. The term includes an individual registered with the board who voluntarily acquired certification as provided in subrule 3.5(2).

"Delivery" means the transport and conveyance of a finished, securely packaged prescription order to the patient or the patient's caregiver.

"Nationally accredited program" means a program and examination for the certification of pharmacy technicians that is accredited by the NCCA.

"NCCA" means the National Commission for Certifying Agencies.

"Nuclear pharmacy technician" means a person who is employed in Iowa by a licensed nuclear pharmacy under the responsibility of an Iowa-licensed qualified nuclear pharmacist to assist in the technical functions of the practice of pharmacy pursuant to 657—Chapter 16.

"Pharmacy technician" or *"technician"* means a person who is employed in Iowa by a licensed pharmacy under the responsibility of an Iowa-licensed pharmacist to assist in the technical functions of the practice of pharmacy, as provided in rules 3.22(155A) through 3.24(155A).

"Pharmacy technician certification" or *"national certification"* means a certificate issued by a national pharmacy technician certification authority accredited by the NCCA attesting that the technician has successfully completed the requirements of the certification program. The term includes evidence of renewal of the national certification. "National certification," as that term relates to a nuclear pharmacy technician working exclusively in an Iowa-licensed nuclear pharmacy, shall be as defined in rule 657—16.2(155A).

"Pharmacy technician trainee" or *"technician trainee"* means an individual who is in training to become a pharmacy technician and who is in the process of acquiring national certification as a pharmacy technician as provided in rule 3.5(155A).

"Pharmacy technician training" or *"technician training"* means education or experience acquired for the purpose of qualifying for and preparing for national certification.

"Supervising pharmacist" means an Iowa-licensed pharmacist who is on duty in an Iowa-licensed pharmacy and who is responsible for the actions of a pharmacy technician or other supportive personnel.

"Supportive personnel" means a person, other than a licensed pharmacist, a registered pharmacist-intern, or a registered pharmacy technician, who may perform nontechnical duties assigned by the pharmacist under the pharmacist's supervision, including delivery, billing, cashier, and clerical functions.

657—3.2(155A) Purpose of registration. A registration program for pharmacy technicians is established for the purposes of determining the competency of a pharmacy technician or of an applicant for registration as a pharmacy technician, a certified technician, or a pharmacy technician trainee and for the purposes of identification, tracking, and disciplinary action for violations of federal or state pharmacy or drug laws or regulations.

657—3.3(155A) Registration required. Any person employed in Iowa as a pharmacy technician, except a pharmacist-intern whose pharmacist-intern registration is in good standing with the board, shall obtain and maintain during such employment a current registration as a pharmacy technician,

certified pharmacy technician, or pharmacy technician trainee pursuant to these rules. An individual accepting employment as a pharmacy technician or technician trainee in Iowa who fails to register as a pharmacy technician, certified technician, or technician trainee as provided by these rules may be subject to disciplinary sanctions.

3.3(1) *Licensed health care provider.* Except as provided in this rule, a licensed health care provider whose registration or license is in good standing with and not subject to current disciplinary sanctions or practice restrictions imposed by the licensee's professional licensing board and who assists in the technical functions of the practice of pharmacy shall be required to register as a pharmacy technician, certified technician, or technician trainee pursuant to these rules.

3.3(2) *Original application required.* Any person not currently registered with the board as a pharmacy technician or certified technician shall complete an application for registration within 30 days of accepting employment in an Iowa pharmacy as a pharmacy technician. Such application shall be received in the board office before the expiration of this 30-day period.

3.3(3) *Technician training.* A person who is enrolled in a college-based or American Society of Health-System Pharmacists (ASHP)-accredited technician training program shall obtain a pharmacy technician trainee registration prior to beginning on-site practical experience. A person who is employed in a pharmacy and who is receiving pharmacy technician training through work experience shall obtain a pharmacy technician trainee registration within 30 days of the commencement of pharmacy technician training.

3.3(4) *Registration number.* Each pharmacy technician, certified technician, and technician trainee registered with the board will be assigned a unique registration number.

657—3.4 Reserved.

657—3.5(155A) Certification of pharmacy technicians. Prior to July 1, 2010, the certification and recertification of pharmacy technicians shall be voluntary and not mandatory. Beginning July 1, 2010, the certification of pharmacy technicians shall be required as provided by this rule. National certification does not supplant the need for licensed pharmacist control over the performance of delegated functions, nor does national certification exempt the pharmacy technician from registration pursuant to these rules.

3.5(1) *Voluntary certification prior to July 1, 2010.* An individual who holds a valid current national certification from the Institute for the Certification of Pharmacy Technicians (ICPT) or the Pharmacy Technician Certification Board (PTCB) and who acquired such certification prior to July 1, 2010, shall be deemed to have met the requirement for national certification beginning July 1, 2010, provided the certification is maintained in current standing.

3.5(2) *Required certification effective July 1, 2010.* Beginning July 1, 2010, a pharmacy technician shall acquire national certification through any NCCA-accredited pharmacy technician certification program and examination, the successful completion of which fulfills the requirement for national certification. National certification of a nuclear pharmacy technician employed solely in the practice of nuclear pharmacy shall be pursuant to certification requirements identified in 657—Chapter 16.

3.5(3) *Pharmacy technician trainee.* Beginning July 1, 2009, a person who is in the process of acquiring national certification as a pharmacy technician shall register with the board as a pharmacy technician trainee. The registration shall be issued for a period of one year and shall not be renewed.

3.5(4) *Certified pharmacy technician.* Beginning July 1, 2010, all applicants for a new pharmacy technician registration, except as provided by subrule 3.5(3), and all applicants for renewal of a pharmacy technician registration shall provide proof of current national pharmacy technician certification and shall complete the application for certified pharmacy technician registration.

657—3.6 and **3.7** Reserved.

657—3.8(155A) Application form.

3.8(1) *Required information.* The application for a pharmacy technician registration, certified technician registration, or pharmacy technician trainee registration shall include the following:

a. Information sufficient to identify the applicant including, but not limited to, name, address, date of birth, gender, and social security number;

b. Educational background;

c. Work experience;

d. Current place or places of employment;

e. Any other information deemed necessary by the board and as provided by this rule.

3.8(2) *Declaration of current impairment or limitations.* The applicant shall declare any current use of drugs, alcohol, or other chemical substances that in any way impairs or limits the applicant's ability to perform the duties of a pharmacy technician with reasonable skill and safety.

3.8(3) *History of felony or misdemeanor crimes.* The applicant shall declare any history of being charged, convicted, found guilty of, or entering a plea of guilty or no contest to a felony or misdemeanor crime (other than minor traffic violations with fines under $100).

3.8(4) *History of disciplinary actions.* The applicant shall declare any history of disciplinary actions or practice restrictions imposed by a state health care professional or technician licensure or registration authority.

3.8(5) *Additional information.* The following additional information shall be required from an applicant for the specified registration.

a. Technician trainee. The applicant for technician trainee registration shall identify the source of technician training, the anticipated date of completion of training, and the anticipated date of national certification.

b. Certified pharmacy technician. The applicant for certified technician registration shall provide proof of current pharmacy technician certification. The applicant shall also identify all current pharmacy employers including pharmacy name, license number, address, and average hours worked per week.

c. Licensed health care provider. In addition to the additional information required by paragraph *"a"* or *"b"* as applicable, a licensed health care provider shall provide evidence that the licensee's professional license or registration is current and in good standing and is not subject to current disciplinary sanctions or practice restrictions imposed by the licensee's professional licensing authority.

3.8(6) *Sworn signature.* The applicant shall sign the application under penalty of perjury and shall submit the application to the board with the appropriate fees pursuant to rule 3.10(155A).

657—3.9(155A) Registration term and renewal. Prior to July 1, 2008, a pharmacy technician registration shall expire on the second last day of the birth month following initial registration, with the exception that a new pharmacy technician registration issued within the two months immediately preceding the applicant's birth month shall expire on the third last day of the birth month following initial registration. A pharmacy technician registration issued between July 1, 2008, and July 1, 2009, except as provided in subrule 3.9(1), shall expire no later than June 30, 2010. Registration shall not require continuing education for renewal.

3.9(1) *Certified pharmacy technician registration.* A certified pharmacy technician registration shall expire on the second last day of the birth month following initial registration, with the exception that a new certified pharmacy technician registration issued within the two months immediately preceding the applicant's birth month shall expire on the third last day of the birth month following initial registration.

3.9(2) *Pharmacy technician trainee registration.* Beginning July 1, 2009, a registration for a pharmacy technician who is in the process of acquiring national certification (technician trainee) shall expire on the last day of the registration month 12 months following the date of registration or 12 months following the date registration was required pursuant to subrule 3.3(3).

a. National certification completed. When the registered technician trainee completes national certification, and no later than the date of expiration of the technician trainee registration, the pharmacy technician trainee shall complete and submit an application for certified pharmacy technician registration. A successful application shall result in issuance of a new certified pharmacy technician registration as provided in subrule 3.9(1).

b. Voluntary cancellation of registration. A registered technician trainee who fails to complete national certification prior to expiration of the technician trainee registration shall notify the board that the pharmacy technician trainee registration should be canceled and that the individual has ceased practice as a pharmacy technician.

c. Failure to notify the board. If a pharmacy technician trainee fails to notify the board prior to the expiration date of the technician trainee registration regarding the individual's intentions as provided in paragraph *"a"* or *"b,"* the technician trainee registration shall be canceled and the individual shall cease practice as a pharmacy technician.

657—3.10(155A) Registration fee. The following fees for initial registration and registration renewal shall apply to the specified registration applications filed within the following time frames. The appropriate fee shall be submitted with the registration application in the form of a personal check, certified check or cashier's check, or a money order payable to the Iowa Board of Pharmacy.

3.10(1) *Registration prior to July 1, 2009.* The fee for obtaining an initial technician registration, for obtaining an initial certified pharmacy technician registration, or for renewal of a technician or certified technician registration prior to July 1, 2009, shall be $40 plus applicable surcharge pursuant to rule 657—30.8(155A).

3.10(2) *Registration beginning July 1, 2009.* The fee for obtaining an initial certified pharmacy technician registration or for biennial renewal of a certified pharmacy technician registration beginning July 1, 2009, shall be $50 plus applicable surcharge pursuant to rule 657—30.8(155A).

3.10(3) *Technician trainee registration beginning July 1, 2009.* The fee for a one-year pharmacy technician trainee registration shall be $20 plus applicable surcharge pursuant to rule 657—30.8(155A).

657—3.11(155A) Late applications and fees.

3.11(1) *Initial registration.* An application for initial registration that is not received within the applicable period specified in subrule 3.3(2) or 3.3(3) shall be delinquent, and the applicant shall be assessed a late payment fee. The late payment fee shall be equal to the amount of the fee for initial registration. A delinquent initial registration shall include payment of the initial registration fee, applicable surcharge pursuant to rule 657—30.8(155A), and late payment fee.

3.11(2) *Registration renewal.* A technician registration that is not renewed before its expiration date shall be delinquent, and the registrant shall not continue employment as a pharmacy technician until the registration is reactivated. An individual who continues employment as a pharmacy technician without a current registration, in addition to the pharmacy and the pharmacist in charge that allow the individual to continue practice as a pharmacy technician, may be subject to disciplinary sanctions.

a. A person who is required to renew a registration pursuant to these rules and who fails to renew the registration before the first day of the month following expiration shall pay the renewal fee, a penalty fee equal to the amount of the renewal fee, plus the applicable surcharge pursuant to rule 657—30.8(155A).

b. A person who is required to renew a registration pursuant to these rules and who fails to renew the registration before the first day of the second month following expiration shall pay the renewal fee, a penalty fee equal to the amount of the renewal fee, the applicable surcharge pursuant to rule 657—30.8(155A), plus an additional penalty fee of $10 for each additional month, not to exceed three additional months, that the registration is delinquent. The maximum combined fee payment for reactivation of a delinquent registration shall not exceed an amount equal to twice the renewal fee plus $30 plus the applicable surcharge pursuant to rule 657—30.8(155A).

657—3.12(155A) Registration certificates. The certificate of technician registration issued by the board to a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee is the property of and shall be maintained by the registered technician. The certificate or a copy of the certificate shall be maintained in each pharmacy where the pharmacy technician, certified pharmacy technician, or pharmacy technician trainee works. Each pharmacy utilizing pharmacy technicians shall be responsible

for verifying that all technicians, certified technicians, and technician trainees working in the pharmacy are registered, and that technician registrations remain current and active.

657—3.13(155A) Notifications to the board. A pharmacy technician, certified pharmacy technician, or technician trainee shall report to the board within ten days a change of the technician's name, address, or pharmacy employment status.

657—3.14 to **3.16** Reserved.

657—3.17(155A) Training and utilization of pharmacy technicians. All Iowa-licensed pharmacies utilizing pharmacy technicians shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians appropriate to the practice of pharmacy. Pharmacy policies shall specify the frequency of review. Technician training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of technician training shall be available for inspection and copying by the board or an agent of the board.

657—3.18(147,155A) Identification of pharmacy technician.

3.18(1) *Identification badge.* A pharmacy technician shall wear a visible identification badge while on duty that clearly identifies the person as a pharmacy technician and that includes at least the technician's first name.

3.18(2) *Misrepresentation prohibited.* A pharmacy technician shall not represent himself or herself in any manner as a pharmacist or pharmacist-intern. A pharmacy technician shall not represent himself or herself in any manner as a certified pharmacy technician unless the technician has attained national pharmacy technician certification. A technician trainee shall not represent himself or herself in any manner as a certified pharmacy technician, as a pharmacist-intern, or as a pharmacist.

657—3.19 Reserved.

657—3.20(155A) Responsibility of supervising pharmacist. The ultimate responsibility for the actions of a pharmacy technician, a certified pharmacy technician, or a pharmacy technician trainee shall remain with the supervising pharmacist.

657—3.21(155A) Delegation of technical functions. A pharmacist may delegate technical dispensing functions to an appropriately trained and registered pharmacy technician, but only if the pharmacist is on site when delegated functions are performed, except as provided in 657—subrule 6.7(2) or 657—subrule 7.6(2), as appropriate, or as provided for telepharmacy in 657—Chapter 9. The pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.

657—3.22(155A) Technical functions. At the discretion of the supervising pharmacist, technical functions which may be delegated to a pharmacy technician, a certified pharmacy technician, or a pharmacy technician trainee include, but are not limited to, the following:

1. Performing packaging, manipulative, or repetitive tasks relating to the processing of a prescription or medication order in a licensed pharmacy.
2. Accepting prescription refill authorizations communicated to a pharmacy by a prescriber or by the prescriber's office.
3. Contacting prescribers to obtain prescription refill authorizations.
4. Collecting pertinent patient information.
5. Entering prescription and patient information into the pharmacy computer system.

6. Inspecting drug supplies provided and controlled by an Iowa-licensed pharmacy, including but not limited to drug supplies maintained in an ambulance or other emergency medical service vehicle, a long-term care facility, a hospital nursing unit, or a hospice facility.

657—3.23(155A) Tasks a pharmacy technician shall not perform. A pharmacy technician, a certified pharmacy technician, or a pharmacy technician trainee shall not:

1. Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;
2. Conduct prospective drug use review or evaluate a patient's medication record for purposes identified in rule 657—8.21(155A);
3. Provide patient counseling, consultation, or patient-specific drug information, tender an offer of patient counseling on behalf of a pharmacist, or accept a refusal of patient counseling from a patient or patient's agent;
4. Make decisions that require a pharmacist's professional judgment, such as interpreting prescription drug orders or applying information;
5. Transfer a prescription drug order to another pharmacy or receive the transfer of a prescription drug order from another pharmacy;
6. Delegate technical functions to supportive personnel.

657—3.24(155A) New prescription drug orders or medication orders. At the discretion of the supervising pharmacist, a pharmacy technician or a certified pharmacy technician may be allowed to accept new prescription drug orders or medication orders communicated to the pharmacy by a prescriber or by the prescriber's agent if the pharmacy technician or certified pharmacy technician has received appropriate training pursuant to the pharmacy's policies and procedures. The supervising pharmacist shall remain responsible for ensuring the accuracy, validity, and completeness of the information received by the pharmacy technician or certified technician. The pharmacist shall contact the prescriber to resolve any questions, inconsistencies, or other issues relating to the information received by the pharmacy technician or certified technician that involve a pharmacist's professional judgment.

657—3.25(155A) Delegation of nontechnical functions. A pharmacist may delegate nontechnical functions to supportive personnel only if the pharmacist is on site when delegated nontechnical functions are performed. A pharmacy technician shall not delegate technical functions to supportive personnel.

657—3.26 and **3.27** Reserved.

657—3.28(147,155A) Unethical conduct or practice. Violation by a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee of any of the provisions of this rule shall constitute unethical conduct or practice and may be grounds for disciplinary action as provided in rule 3.30(155A).

3.28(1) *Misrepresentative deeds.* A pharmacy technician, certified technician, or technician trainee shall not make any statement tending 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.

3.28(2) *Confidentiality.* In the absence of express written authorization from the patient or written order or direction of a court, except where the best interests of the patient require, a pharmacy technician, certified technician, or technician trainee shall not divulge or reveal to any person other than the patient or the patient's authorized representative, the prescriber or other licensed practitioner then caring for the patient, a licensed pharmacist, a person duly authorized by law to receive such information, or as otherwise provided in rule 657—8.16(124,155A), any of the following:

a. A patient's name, address, social security number, or any information that could be used to identify a patient;

b. The contents of any prescription drug order or medication order or the therapeutic effect thereof, or the nature of professional pharmaceutical services rendered to a patient;

c. The nature, extent, or degree of illness suffered by any patient; or

d. Any medical information furnished by the prescriber or the patient.

3.28(3) *Discrimination.* It is unethical to unlawfully discriminate between patients or groups of patients for reasons of religion, race, creed, color, gender, gender identity, sexual orientation, marital status, age, national origin, physical or mental disability, or disease state when providing pharmaceutical services.

3.28(4) *Unethical conduct or behavior.* A pharmacy technician, certified technician, or technician trainee shall not exhibit unethical behavior in connection with the technician's pharmacy employment. Unethical behavior shall include, but is not limited to, the following acts: verbal or physical abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.

657—3.29(155A) Denial of registration. The executive director or designee may deny an application for registration as a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205 or any rule of the board.

An individual whose application for registration as a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee is denied pursuant to this rule may, within 30 days after issuance of the notice of denial, appeal to the board for reconsideration of the application.

657—3.30(155A) Discipline of pharmacy technicians.

3.30(1) *Violations.* The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205 or any rule of the board.

3.30(2) *Sanctions.* The board may impose the following disciplinary sanctions:

a. Revocation of a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee registration.

b. Suspension of a pharmacy technician, certified pharmacy technician, or pharmacy technician trainee registration until further order of the board or for a specified period.

c. Nonrenewal of a pharmacy technician or certified pharmacy technician registration.

d. Prohibition, permanently, until further order of the board, or for a specified period, from engaging in specified procedures, methods, or acts.

e. Probation.

f. The ordering of a physical or mental examination.

g. The imposition of civil penalties not to exceed $25,000.

h. Issuance of a citation and warning.

i. Such other sanctions allowed by law as may be appropriate.

These rules are intended to implement Iowa Code sections 147.72, 155A.23, 155A.33, and 155A.39 and Iowa Code Supplement sections 155A.6 and 155A.6A.

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CHAPTER 4
PHARMACIST-INTERNS
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 3]

657—4.1(155A) Definitions.

"Board" means the Iowa board of pharmacy examiners.

"Internship booklet" means a set of documents and forms to be completed by one or more pharmacist preceptors during the course of an individual pharmacist-intern's internship training. The booklet includes the intern's registration certificate, instructions for the intern and the preceptor, the competencies to be attained by the intern and certified by each preceptor, and one or more affidavits on which each preceptor shall certify the hours of nonconcurrent internship completed under that preceptor's supervision.

"Nontraditional internship booklet" means that internship booklet comprised of competencies and affidavits relating exclusively to that nontraditional internship segment and approved by the board for the individual pharmacist-intern pursuant to subrule 4.6(5).

"Pharmacist-intern" or *"intern"* means a person enrolled in a college of pharmacy or actively pursuing a pharmacy degree, or as otherwise provided by the board, who is registered with the board for the purpose of obtaining instruction in the practice of pharmacy from a preceptor pursuant to Iowa Code section 155A.6. "Pharmacist-intern" includes a graduate of an approved college of pharmacy, or a foreign graduate who has established educational equivalency pursuant to the requirements of rule 4.7(155A), who is registered with the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist in Iowa. "Pharmacist-intern" may include an individual participating in a residency or fellowship program in Iowa, whether or not the individual is licensed as a pharmacist in another state.

"Pharmacist preceptor" or *"preceptor"* means a pharmacist licensed to practice pharmacy whose license is current and in good standing. Preceptors shall meet the conditions and requirements of rule 4.9(155A). No pharmacist shall serve as a preceptor while the pharmacist's license to practice pharmacy is the subject of disciplinary sanction by a pharmacist licensing authority.

657—4.2(155A) Goal and objectives of internship.

4.2(1) *Goal.* The goal of internship is for the pharmacist-intern, over a period of time, to attain and build upon the knowledge, skills, responsibilities, and ability to safely, efficiently, and effectively practice pharmacy under the laws and rules of the state of Iowa.

4.2(2) *Objectives.* The objectives of internship are as follows:

a. Managing drug therapy to optimize patient outcomes. The pharmacist-intern shall evaluate the patient and patient information to determine the presence of a disease or medical condition, to determine the need for treatment or referral, and to identify patient-specific factors that affect health, pharmacotherapy, or disease management; ensure the appropriateness of the patient's specific pharmacotherapeutic agents, dosing regimens, dosage forms, routes of administration, and delivery systems; and monitor the patient and patient information and manage the drug regimen to promote health and ensure safe and effective pharmacotherapy.

b. Ensuring the safe and accurate preparation and dispensing of medications. The pharmacist-intern shall perform calculations required to compound, dispense, and administer medication; select and dispense medications; and prepare and compound extemporaneous preparations and sterile products.

c. Providing drug information and promoting public health. The pharmacist-intern shall access, evaluate, and apply information to promote optimal health care; educate patients and health care professionals regarding prescription medications, nonprescription medications, and medical devices; and educate patients and the public regarding wellness, disease states, and medical conditions.

d. Adhering to professional and ethical standards. The pharmacist-intern shall comply with professional, legal, moral, and ethical standards relating to the practice of pharmacy and the operation of the pharmacy.

e. Understanding the management of pharmacy operations. The pharmacist-intern shall develop a general understanding of the business procedures of a pharmacy and develop knowledge concerning the employment and supervision of pharmacy employees.

657—4.3(155A) 1500-hour requirements. Internship credit may be obtained only after internship registration with the board and successful completion of one semester in a college of pharmacy. Internship shall consist of a minimum of 1500 hours, 1250 hours of which may be a college-based clinical program approved or accepted by the board. Programs shall be structured to provide experience in community, institutional, and clinical pharmacy practices. The remaining 250 hours shall be acquired under the supervision of one or more preceptors in a traditional licensed general or hospital pharmacy, at a rate of no more than 48 hours per week, where the goal and objectives of internship in rule 4.2(155A) apply. Credit toward the 250 hours will be allowed, at a rate not to exceed 10 hours per week, for an internship served concurrent with academic training. "Concurrent time" means internship experience acquired while the person is a full-time student carrying, in a given school term, at least 75 percent of the average number of credit hours per term needed to graduate and receive an entry level degree in pharmacy. Recognized academic holiday periods, such as spring break and Christmas break, shall not be considered "concurrent time." The competencies in subrule 4.2(2) shall not apply to college-based clinical programs.

657—4.4(155A) Iowa colleges of pharmacy clinical internship programs. The board shall periodically review the clinical component of internship programs of the colleges of pharmacy located in Iowa. The board reserves the right to set conditions relating to the approval of such programs.

657—4.5(155A) Out-of-state internship programs. Candidates enrolled in out-of-state colleges of pharmacy who complete the internship requirements of that state shall be deemed to have satisfied Iowa's internship requirements. Candidates shall submit documentation from the out-of-state internship program certifying completion of that state's requirements. Candidates enrolled in colleges of pharmacy located in states with no formal internship training program shall submit documentation from that state's board of pharmacy or college of pharmacy certifying that the candidate has completed all prelicensure training requirements.

657—4.6(155A) Registration, reporting, and authorized functions. Every person shall register with the board before beginning the person's internship experience, whether or not for the purpose of fulfilling the requirements of rule 4.3(155A). Registration is required of all students enrolled in Iowa colleges of pharmacy after they have successfully completed one semester in the college of pharmacy. Colleges of pharmacy located in Iowa shall, at least annually, certify to the board the names of students who have successfully completed one semester in the college of pharmacy or who have withdrawn from the college of pharmacy.

4.6(1) *Supervision and authorized functions.* A licensed pharmacist shall be on duty in the pharmacy and shall be responsible for the actions of a pharmacist-intern during all periods of internship training. The following judgmental functions, usually restricted to a pharmacist, may be delegated to pharmacist-interns registered by the board:

a. Verification of the accuracy, validity, and appropriateness of the filled prescription or medication order;

b. Review and assessment of patient records for purposes identified in rule 657—8.21(155A);

c. Patient counseling.

4.6(2) *Term of registration.* Registration shall remain in effect as long as the board is satisfied that the intern is pursuing a degree in pharmacy in good faith and with reasonable diligence. A pharmacist-intern may request that the intern's registration be extended beyond the automatic termination of the registration pursuant to the procedures and requirements of 657—Chapter 34. Except as provided by the definition of pharmacist-intern in rule 4.1(155A), registration shall automatically terminate upon the earliest of any of the following:

a. Licensure to practice pharmacy in any state;

b. Lapse, exceeding one year, in the pursuit of a degree in pharmacy; or

c. One year following graduation from the college of pharmacy.

4.6(3) *Identification, reports, and notifications.* Credit for internship time will not be granted unless registration and other required records and affidavits are completed.

a. The pharmacist-intern shall be so designated in all relationships with the public and health professionals. While on duty in the pharmacy, the intern shall wear visible to the public a name badge including the designation "pharmacist-intern" or "pharmacy student."

b. Registered interns shall notify the board office within ten days of a change of name or address.

c. Notarized affidavits of experience in non-college-sponsored programs shall be filed with the board office after the successful completion of the appropriate internship booklet and completion of all required internships. These affidavits shall include certification of competencies and shall certify only the number of hours and dates of training as provided in rule 4.3(155A). An individual registered as a pharmacist-intern while participating in an Iowa residency or fellowship program shall not be required to file affidavits of experience or to submit certification of competencies.

4.6(4) *No credit prior to registration.* Credit will not be given for internship experience obtained prior to the individual's registration as a pharmacist-intern. Credit for Iowa college-based clinical programs (1250 hours) will not be granted unless registration is issued before the student begins the program.

4.6(5) *Nontraditional internship.* Internship training at any site which is not licensed as a general or hospital pharmacy is considered nontraditional internship.

a. Application. Prior to beginning a period of nontraditional internship, the intern shall submit a written application, on forms provided by the board, for approval of the objectives of the nontraditional internship. The application shall identify objectives consistent with the unique learning experiences of the intern and consistent with the goal and objectives of internship in rule 4.2(155A).

b. Preceptor. A preceptor supervising a pharmacist-intern in a nontraditional internship shall be a currently licensed pharmacist in the state where the internship is served, and the requirements of rule 4.9(155A) shall apply to all preceptors.

c. Certification, not credit. Hours obtained in nontraditional internship shall not be credited toward the total 1500 hours required pursuant to rule 4.3(155A) prior to licensure to practice pharmacy in Iowa. The board may, however, certify hours obtained in one or more approved nontraditional internships in recognition of the pharmacist-intern's training outside the scope of traditional pharmacy practice. Certification shall not be granted for experience obtained in a nontraditional internship unless the board, prior to the intern's beginning the period of internship, approved the objectives of the internship.

657—4.7(155A) Foreign pharmacy graduates. Foreign pharmacy graduates who are candidates for licensure in Iowa will be required to obtain a minimum of 1500 hours of internship in a licensed pharmacy or other board-approved location. These candidates shall register with the board as provided in rule 4.6(155A). Internship credit will not be granted until the candidate has been issued an intern registration. Applications for registration shall be accompanied by certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC) as provided in 657—subrule 2.10(1). The board may grant credit to a foreign pharmacy graduate, based on the candidate's experience in the practice of pharmacy, for all or any portion of the required 1500 hours of internship training. The candidate shall provide detailed information regarding the candidate's experience in the practice of pharmacy. The board shall determine, on a case-by-case basis, whether and to what extent the candidate's experience meets the goals and objectives established in rule 4.2(155A).

657—4.8(155A) Fees. The fee for registration as a pharmacist-intern is $30, plus applicable surcharge pursuant to 657—30.8(155A), which shall be payable with the application.

657—4.9(155A) Preceptor requirements.

4.9(1) *Licensed pharmacist.* A preceptor shall be a licensed pharmacist in good standing in the state where the internship is to be served pursuant to the definition of pharmacist preceptor in rule 4.1(155A).

4.9(2) *Competencies and affidavits.* A preceptor shall be responsible for initialing and dating those competencies the intern attained under the supervision of the preceptor and for completing the affidavit certifying the number of hours and the dates of each internship training period under the supervision of the preceptor.

4.9(3) *Number of interns.* A preceptor may supervise no more than two pharmacist-interns concurrently.

4.9(4) *Responsibility.* A preceptor shall be responsible for all functions performed by a pharmacist-intern.

657—4.10(155A) Denial of pharmacist-intern registration. The board may deny an application for registration as a pharmacist-intern for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs, or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A or 205, or any rule of the board.

657—4.11(155A) Discipline of pharmacist-interns.

4.11(1) *Grounds for discipline.* The board may impose discipline for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs or for any violation of Iowa Code chapter 124, 124A, 124B, 126, 147, 155A, or 205, or any rule of the board.

4.11(2) *Sanctions.* The board may impose the following disciplinary sanctions:

a. Revocation of a pharmacist-intern registration.

b. Suspension of a pharmacist-intern registration until further order of the board or for a specified period.

c. Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods, or acts.

d. Such other sanctions allowed by law as may be appropriate.

These rules are intended to implement Iowa Code section 155A.6.

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CHAPTER 5
LICENSURE BY RECIPROCITY

[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 5]

Rescinded IAB 9/4/02, effective 10/9/02

CHAPTER 6
GENERAL PHARMACY PRACTICE
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 2]

657—6.1(155A) Purpose and scope. A general pharmacy is a location where a pharmacist provides pharmaceutical services or dispenses pharmaceutical products to patients in accordance with pharmacy laws. This chapter does not apply to a hospital pharmacy as defined in 657—Chapter 7. The requirements of these rules for general pharmacy practice are in addition to the requirements of 657—Chapter 8 and other rules of the board relating to services provided by the pharmacy.

657—6.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the following:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.
3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.
4. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657—8.21(155A).
5. Ensuring that a pharmacist provides patient counseling as specified in rule 6.14(155A).
6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.
7. Delivering drugs to the patient or the patient's agent.
8. Ensuring that patient medication records are maintained as specified in rule 6.13(155A).
9. Training pharmacy technicians and supportive personnel.
10. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.
11. Distributing and disposing of drugs from the pharmacy.
12. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.
13. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs.
14. Establishing and implementing policies and procedures for all operations of the pharmacy.
15. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.
16. Ensuring that there is adequate space within the prescription department or a locked room not accessible to the public for the storage of prescription drugs, devices, and controlled substances and to support the operations of the pharmacy.

657—6.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. The Iowa Pharmacy Law and Information Manual.
2. A patient information reference that includes or provides patient information in compliance with rule 6.14(155A).
3. A reference on drug interactions.
4. A general information reference.
5. A drug equivalency reference.
6. A reference on natural or herbal medicines.
7. The readily accessible telephone number of a poison control center that serves the area.

8. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—6.4(155A) Exemption from duplicate requirements. A pharmacy established in the same location as another licensed pharmacy and with direct and immediate access to required references, patient counseling area, refrigerator, or sink with hot and cold running water may utilize the references, counseling area, refrigerator, or sink of the other pharmacy to satisfy the requirements of rule 6.3(155A), subrule 6.14(3), or rule 657—8.5(155A), paragraphs "1" and "2."

657—6.5 and **6.6** Reserved.

657—6.7(124,155A) Security. While on duty, each pharmacist shall be responsible for the security of the prescription department, including provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, records for such drugs, and patient records as provided in 657—Chapter 21.

6.7(1) *Department locked.* The prescription department shall be locked by key or combination so as to prevent access when a pharmacist is not on site except as provided in subrule 6.7(2).

6.7(2) *Temporary absence of pharmacist.* In the temporary absence of the pharmacist, only the pharmacist in charge may designate persons who may be present in the prescription department to perform technical and nontechnical functions designated by the pharmacist in charge. Activities identified in subrule 6.7(3) may not be performed during such temporary absence of the pharmacist. A temporary absence is an absence of short duration not to exceed two hours. In the absence of the pharmacist, the pharmacy shall notify the public that the pharmacist is temporarily absent and that no prescriptions will be dispensed until the pharmacist returns.

6.7(3) *Activities prohibited in absence of pharmacist.* Activities which shall not be designated and shall not be performed during the temporary absence of the pharmacist include:

a. Dispensing or distributing any prescription drugs or devices to patients or others.

b. Providing the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

c. Conducting prospective drug use review or evaluating a patient's medication record for purposes identified in rule 657—8.21(155A).

d. Providing patient counseling, consultation, or drug information.

e. Making decisions that require a pharmacist's professional judgment such as interpreting or applying information.

f. Transferring prescriptions to or from other pharmacies.

657—6.8(124,155A) Prescription processing documentation. All prescriptions shall be dated and assigned a unique identification number that shall be recorded on the original prescription. The original prescription, whether transmitted orally, electronically, or in writing, shall be retained by the pharmacy filling the prescription. Refill documentation shall include date of refill and the initials or other unique identification of the pharmacist. The name, strength, and either the manufacturer's name or the National Drug Code (NDC) of the actual drug product dispensed shall be maintained and be readily retrievable.

657—6.9(124,155A) Transfer of prescription. The transmission of a prescription drug order from a pharmacy to a pharmacy engaged in centralized prescription filling or processing on behalf of the originating pharmacy pursuant to the requirements of 657—Chapter 18 shall not constitute the transfer of a prescription. Upon the request of a patient or the patient's caregiver, a pharmacy shall transfer original prescription drug order information and prescription refill information to a pharmacy designated by the patient or the patient's caregiver, central fill or processing pharmacies excepted, subject to the following requirements:

6.9(1) *Schedule III, IV, or V prescriptions.* The transfer of original prescription drug order information for controlled substances listed in Schedule III, IV, or V is permissible between pharmacies on a one-time basis except as provided in subrule 6.9(9).

6.9(2) *Noncontrolled substances prescriptions.* The transfer of original prescription drug order information for noncontrolled prescription drugs between pharmacies is permissible as long as the number of transfers does not exceed the number of originally authorized refills and the original prescription is still valid.

6.9(3) *Communication.* The transfer is communicated directly between pharmacists, directly between pharmacist-interns under the direct supervision of pharmacists at the respective pharmacies, directly between a pharmacist and a pharmacist-intern under the direct supervision of a pharmacist, or as authorized in subrule 6.9(9).

6.9(4) *Prescriptions maintained.* Both the original and the transferred prescription drug orders are maintained for a period of two years from the date of last refill.

6.9(5) *Record of transfer out.* The pharmacist or pharmacist-intern transferring the prescription drug order information shall:

a. Invalidate the prescription drug order;

b. Record on or with the invalidated prescription drug order the following information:

(1) The name, address, and, for a controlled substance, the DEA registration number of the pharmacy to which such prescription is transferred;

(2) The name of the pharmacist or pharmacist-intern receiving the prescription drug order information;

(3) The name of the pharmacist or pharmacist-intern transferring the prescription drug order information; and

(4) The date of the transfer.

6.9(6) *Original prescription status.* The original prescription drug order shall be invalidated in the data processing system for purposes of filling or refilling, but shall be maintained in the data processing system for refill history purposes.

6.9(7) *Controlled substance prescription status.* The data processing system shall have a mechanism to prohibit the transfer or refilling of controlled substance prescription drug orders that have been previously transferred.

6.9(8) *Record of transfer received.* The pharmacist or pharmacist-intern receiving the transferred prescription drug order information shall:

a. Indicate that the prescription drug order has been transferred;

b. Record on or with the transferred prescription drug order the following information:

(1) Original date of issuance and date of dispensing, if different from date of issuance;

(2) Original prescription number;

(3) Number of valid refills remaining, the date of last refill, and, for a controlled substance, the dates and locations of all previous refills;

(4) Name, address, and, for a controlled substance, the DEA registration number of the pharmacy from which such prescription drug order information is transferred;

(5) The date of the transfer;

(6) Name of the pharmacist or pharmacist-intern receiving the prescription drug order information;

(7) Name of the pharmacist or pharmacist-intern transferring the prescription drug order information; and

(8) If transferring a controlled substance prescription from a pharmacy utilizing a shared electronic database system as described in subrule 6.9(9) to a pharmacy outside that shared system, the pharmacy name, location, DEA registration number, and prescription number from which the prescription was originally filled.

6.9(9) *Electronic transfer between pharmacies.* Pharmacies electronically accessing the same prescription drug order records via a real-time, on-line database may electronically transfer prescription information, including controlled substance prescription information, up to the maximum refills permitted by law and the prescriber's authorization, if the following requirements are met.

a. The data processing system shall have a mechanism to send the transferring pharmacy a message containing the following information:

(1) The fact that the prescription drug order was transferred;

(2) The unique identification number of the prescription drug order transferred;

(3) The name, address, and DEA registration number of the pharmacy to which the prescription drug order was transferred and the name of the pharmacist or pharmacist-intern receiving the prescription information; and

(4) The date and time of transfer.

b. A pharmacist or pharmacist-intern under the direct supervision of a pharmacist in the transferring pharmacy shall review the message and document the review by signing and dating a hard copy of the message or logbook containing the information required on the message, or by a notation in the electronic message that includes the unique identification of the pharmacist or pharmacist-intern and the date of review, as soon as practical, but in no event more than 72 hours from the time of such transfer.

c. For transfers of controlled substance prescriptions, all information requirements included in subrules 6.9(1) and 6.9(3) through 6.9(8) shall be satisfied in the electronic system. Transfers of controlled substance prescriptions shall also identify the pharmacy name, address, DEA registration number, and prescription number from which the prescription was originally filled.

[**ARC 7634B**, IAB 3/11/09, effective 4/15/09; **ARC 8169B**, IAB 9/23/09, effective 10/28/09]

657—6.10(126,155A) Prescription label requirements.

6.10(1) *Required information.* The label affixed to or on the dispensing container of any prescription drug or device dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:

a. Serial number (a unique identification number of the prescription);

b. The name, telephone number, and address of the pharmacy;

c. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

d. The name of the prescribing practitioner;

e. The date the prescription is dispensed;

f. The directions or instructions for use, including precautions to be observed;

g. Unless otherwise directed by the prescriber, the label shall bear the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)."

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)";

h. The initials or other unique identification of the dispensing pharmacist.

6.10(2) *Exceptions.* The requirements of subrule 6.10(1) do not apply to unit dose dispensing systems, 657—22.1(155A); sterile products, 657—Chapter 13; and patient med paks, 657—22.5(126,155A).

657—6.11 and **6.12** Reserved.

657—6.13(155A) Patient record system.

6.13(1) *Information required.* A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for obtaining, recording, and maintaining the following information:

a. Full name of the patient for whom the drug is intended;

b. Address and telephone number of the patient;

c. Patient's age or date of birth;

d. Patient's gender;

e. Known allergies;

f. Significant patient information including a list of all prescription drug orders dispensed by the pharmacy during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and

g. Pharmacist comments relevant to the individual's drug therapy, including:

(1) Known drug reactions,

(2) Identified idiosyncrasies,

(3) Known chronic conditions or disease states of the patient,

(4) The identity of any other drugs, over-the-counter drugs, herbals, other alternative medications, or devices currently being used by the patient that may relate to prospective drug review.

6.13(2) *Record retained.* A patient record shall be maintained for a period of not less than two years from the date of the last entry in the patient record. This record may be a hard copy or a computerized form.

6.13(3) *Confidential.* Information in the patient record shall be deemed to be confidential and may be released only as provided in rule 657—8.16(124,155A).

657—6.14(155A) Patient counseling and instruction.

6.14(1) *Counseling required.* Upon receipt of a new prescription drug order and following a prospective drug use review pursuant to 657—8.21(155A), a pharmacist shall counsel each patient or patient's caregiver. An offer to counsel shall not fulfill the requirements of this rule. Patient counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

a. The name and description of the drug;

b. The dosage form, dose, route of administration, and duration of drug therapy;

c. Intended use of the drug, if known, and expected action;

d. Special directions and precautions for preparation, administration, and use by the patient;

e. Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

f. Techniques for self-monitoring drug therapy;

g. Proper storage;

h. Prescription refill information;

i. Action to be taken in the event of a missed dose;

j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

6.14(2) *Instruction.* A pharmacist may instruct patients and demonstrate procedures for self-monitoring of medical conditions and for self-administration of drugs.

6.14(3) *Counseling area.* A pharmacy shall contain an area which is suitable for confidential patient counseling. Such area shall:

a. Be easily accessible to both patient and pharmacists and not allow patient access to prescription drugs;

b. Be designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

6.14(4) *Oral counseling not practicable.* If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may use alternative forms of patient information. "Not practicable" refers to patient variables including, but not limited to, the absence of the patient or patient's caregiver, the patient's or caregiver's hearing impairment, or a language barrier. "Not practicable" does not include pharmacy variables such as inadequate staffing, technology failure, or high prescription volume. Alternative forms of patient information may include written information leaflets, pictogram labels, video programs, or information generated by electronic data processing equipment. When used in place of oral counseling, alternative forms of patient information shall advise the patient or caregiver

that the pharmacist may be contacted for consultation in person at the pharmacy by toll-free telephone or collect telephone call. A combination of oral counseling and alternative forms of counseling is encouraged.

6.14(5) *Exception.* Patient counseling, as described above, shall not be required for inpatients of an institution where other licensed health care professionals are authorized to administer the drugs.

6.14(6) *Refusal of consultation.* A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient's or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

657—6.15(124,126) Return of drugs and other items. For the protection of the public health and safety, prescription drugs and devices, controlled substances, and items of personal contact nature may be returned to the pharmacy for reuse or resale only as herein provided:

6.15(1) *Integrity maintained.* Prescription drugs and devices may be returned, exchanged, or resold only if, in the professional judgment of the pharmacist, the integrity of the prescription drug has not in any way been compromised.

6.15(2) *Controlled substances.* Under no circumstances shall pharmacy personnel accept from a patient or a patient's agent any controlled substances for return, exchange, or resale except to the same patient.

6.15(3) *Unit dose returns.* Prescription drugs dispensed in unit dose packaging, excluding controlled substances, may be returned and reused as authorized in 657—subrule 22.1(6).

6.15(4) *Personal contact items.* Pharmacy personnel shall not accept for reuse or resale any items of personal contact nature that have been removed from the original package or container after sale.

657—6.16(124,155A) Records. Every inventory or other record required to be kept under Iowa Code chapters 124 and 155A or rules of the board shall be kept by the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record except as specifically identified by law or rule. Controlled substance records shall be maintained in a readily retrievable manner in accordance with federal requirements and 657—Chapter 10.

6.16(1) *Combined records.* If controlled substances, prescription drugs, or nonprescription drug items are listed on the same record, the controlled substances shall be asterisked, red-lined, or in some other manner made readily identifiable from all other items appearing on the records.

6.16(2) *Prescriptions maintained.* The original prescription drug order shall be maintained for a period of two years following the date of last activity on the prescription.

6.16(3) *Number imprinted.* The original hard-copy prescription shall be imprinted with the prescription or control number assigned to the prescription drug order.

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;

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.

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09]

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 126.10, 126.11, 155A.6, 155A.13, 155A.27, 155A.28, 155A.31, and 155A.33 through 155A.36.

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◊ Two or more ARCs

CHAPTER 7
HOSPITAL PHARMACY PRACTICE
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 12]

657—7.1(155A) Purpose and scope. Hospital pharmacy means and includes a pharmacy licensed by the board and located within any hospital, health system, institution, or establishment which maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may or may not be admitted for overnight stay at the facility. A hospital is a facility licensed pursuant to Iowa Code chapter 135B. This chapter does not apply to a pharmacy located within such a facility for the purpose of providing outpatient prescriptions. A pharmacy providing outpatient prescriptions is and shall be licensed as a general pharmacy subject to the requirements of 657—Chapter 6. The requirements of these rules for hospital pharmacy practice apply to all hospitals, regardless of size or type, and are in addition to the requirements of 657—Chapter 8 and other rules of the board relating to services provided by the pharmacy.

657—7.2(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the items identified in this rule. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge. Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an "on call" basis. The pharmacist in charge, at a minimum, shall be responsible for:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services.
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy and sufficient to ensure adequate levels of quality patient care services. Drug dispensing by nonpharmacists shall be minimized and eliminated wherever possible.
3. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.
4. Ensuring that a pharmacist performs therapeutic drug monitoring and drug use evaluation.
5. Ensuring that a pharmacist provides drug information to other health professionals and to patients.
6. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.
7. Delivering drugs to the patient or the patient's agent.
8. Ensuring that patient medication records are maintained as specified in rule 7.10(124,155A).
9. Training pharmacy technicians and supportive personnel.
10. Ensuring adequate and appropriate pharmacist oversight and supervision of pharmacy technicians and supportive personnel.
11. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.
12. Distributing and disposing of drugs from the pharmacy.
13. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations.
14. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, controlled substances, and records for such drugs.
15. Preparing a written operations manual governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; and ensuring that all pharmacy personnel are familiar with the contents of the manual.
16. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

657—7.3(155A) Reference library. References may be printed or computer-accessed. A reference library shall be maintained which includes, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. The Iowa Pharmacy Law and Information Manual.
2. A patient information reference that includes or provides patient information in compliance with rule 657—6.14(155A).
3. A reference on drug interactions.
4. A general information reference.
5. A drug equivalency reference.
6. An injectable-drug compatibility reference.
7. A drug identification reference to enable identification of drugs brought into the facility by patients.
8. The readily accessible telephone number of a poison control center that serves the area.
9. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served. For example, the treatment of pediatric patients and oncology patients would require additional references unique to those specialties.

657—7.4 and **7.5** Reserved.

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 the pharmacy:

7.6(1) *Pharmacist responsibility.* Each pharmacist, while on duty, shall be responsible for the security of the pharmacy area, including provisions for effective control against theft of, diversion of, or unauthorized access to drugs or devices, controlled substances, records for such drugs, and patient records as provided in 657—Chapter 21. Policies and procedures shall identify the minimum amount of time that a pharmacist is available at the hospital pharmacy.

7.6(2) *Access when pharmacist absent.* When the pharmacist is absent from the facility, the pharmacy is closed. Policies and procedures shall be established that identify who will have access to the pharmacy when the pharmacy is closed and the procedures to be followed for obtaining drugs, devices, and chemicals to fill an emergent need during the pharmacist's absence.

a. The pharmacist in charge may designate pharmacy technicians who may be present in the pharmacy to perform technical and nontechnical functions designated by the pharmacist in charge. Activities identified in paragraph *"d"* of this subrule may not be performed when the pharmacy is closed.

b. If the pharmacist in charge has authorized the presence in the pharmacy of a pharmacy technician to perform designated functions when the pharmacy is closed, the technician may assist another authorized, licensed health care professional to locate a drug or device pursuant to an emergent need. The pharmacy technician may not dispense or deliver the drug, chemical, or device to the licensed health care professional. The licensed health care professional shall comply with established policies and procedures for obtaining drugs, devices, and chemicals when the pharmacy is closed. The licensed health care professional shall not ask or expect the pharmacy technician to verify that the appropriate drug, chemical, or device has been obtained from the pharmacy.

c. A pharmacy technician who is present in the pharmacy when the pharmacy is closed shall prepare and maintain in the pharmacy a log identifying each period of time that the technician worked in the pharmacy while the pharmacy was closed and identifying each activity performed during that time period. Each entry shall be dated and each daily record shall be signed by the pharmacy technician who prepared the record. The log shall be periodically reviewed by the pharmacist in charge.

d. Activities which shall not be performed by a pharmacy technician when the pharmacist is absent from the facility include:

(1) Dispensing, delivering, or distributing any prescription drugs or devices to patients or others, including health care professionals, prior to pharmacist verification. Verification by a nurse or other licensed health care professional shall not supplant verification by a pharmacist.

(2) Providing the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order.

(3) Conducting prospective drug use review or evaluating a patient's medication record for purposes identified in rule 657—8.21(155A).

(4) Providing patient counseling, consultation, or drug information.

(5) Making decisions that require a pharmacist's professional judgment such as interpreting or applying information.

(6) Preparing compounded drug products for immediate administration by other hospital staff or health care professionals without verification by a pharmacist.

7.6(3) *Locked areas.* All pharmacy areas where drugs or devices are maintained or stored and where a pharmacist is not continually present shall be locked.

7.6(4) *Verification by pharmacist.* When the pharmacy is open, patient-specific drugs or devices shall not be distributed prior to the pharmacist's final verification and approval.

7.6(5) *Drugs or devices in patient care areas.* Drugs or devices maintained or stored in patient care areas shall be in locked storage unless the patient care unit is staffed by health care personnel and the medication area is visible to staff at all times.

657—7.7(155A) Verification by pharmacist when pharmacy is closed. A hospital pharmacy may contract with another pharmacy for remote pharmacist preview and verification of patient-specific drugs or devices ordered for a patient when the hospital pharmacy is closed. Contracted services may include pharmacist order entry pursuant to subrule 7.8(3). Pharmacies entering into a contract or agreement pursuant to this rule shall comply with the following requirements:

7.7(1) *Nonsupplanting service.* A contract or agreement for remote pharmacist services shall not relieve the hospital pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services within the facility. The activities authorized by this rule are intended to supplement hospital pharmacy services when the pharmacy is closed and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist.

7.7(2) *Hospital-staff pharmacist.* Nothing in this rule shall prohibit a pharmacist employed by or contracting with a hospital pharmacy for on-site services from also providing remote preview and verification of patient-specific drugs or devices ordered for a patient when the hospital pharmacy is closed. A pharmacist previewing and verifying drug or device orders from a remote location shall have access to patient information pursuant to subrule 7.7(4) or 7.7(5), shall have access to the prescriber as provided in subrule 7.7(6), and shall be identified on the drug or device order as provided in subrule 7.7(7).

7.7(3) *Licenses required.* A pharmacy contracting with a hospital pharmacy to provide services pursuant to this rule shall maintain with the board a current Iowa pharmacy license. A remote pharmacist providing pharmacy services as an employee or agent of a contracting pharmacy pursuant to this rule shall be licensed to practice pharmacy in Iowa.

7.7(4) *Electronic access to patient information.* The remote pharmacist shall have secure electronic access to the hospital pharmacy's patient information system and to all other electronic systems that the on-site pharmacist has access to when the pharmacy is open. The remote pharmacist shall receive training in the use of the hospital's electronic systems.

7.7(5) *Nonelectronic patient information.* If a hospital's patient information is not maintained in an electronic data system or if the hospital pharmacy is not able to provide remote electronic access to the patient information system, the hospital pharmacy may petition for a waiver of subrule 7.7(4) pursuant to 657—Chapter 34 and this subrule. In addition to the information required pursuant to 657—Chapter 34, the petition for waiver shall identify the hospital pharmacy's alternative to the electronic sharing of patient information, shall explain in detail how the alternative method will ensure timely provision of patient information necessary for the remote pharmacist to effectively review the patient's drug regimen

and history, and shall detail the processes involved in the alternative proposal including identification of all individuals involved in each of those processes.

7.7(6) *Access to prescriber.* The remote pharmacist shall be able to contact the prescriber to discuss any concerns identified during the pharmacist's review of the patient's information.

7.7(7) *Pharmacist identified.* The record of each patient-specific drug or device order processed pursuant to this rule shall identify, by name or other unique identifier, each pharmacist involved in the preview and verification of the order.

657—7.8(124,126,155A) Drug distribution and control. Policies and procedures governing drug distribution and control shall be developed by the pharmacist in charge with input from other involved hospital staff such as physicians and nurses, from committees such as the pharmacy and therapeutics committee or its equivalent, and from any related patient care committee. It is essential that the pharmacist in charge or designee routinely be available to or on all patient care areas to establish rapport with the personnel and to become familiar with and contribute to medical and nursing procedures relating to drugs.

7.8(1) *Drug preparation.* The pharmacist shall institute the control procedures needed to ensure that patients receive the correct drugs at the proper times. Adequate quality assurance procedures shall be developed.

a. Hospitals shall utilize a unit dose dispensing system pursuant to rule 657—22.1(155A). All drugs dispensed by the pharmacist for administration to patients shall be in single unit or unit dose packages if practicable unless the dosage form or drug delivery device makes it impracticable to package the drug in a unit dose or single unit package.

(1) The pharmacist in charge shall establish policies and procedures that identify situations when drugs may be dispensed in other than unit dose or single unit packages outside the unit dose dispensing system.

(2) The need for nurses to manipulate drugs prior to their administration shall be minimized.

b. Pharmacy personnel shall, except as specified in policies and procedures, prepare all sterile products in conformance with 657—Chapter 13.

c. Pharmacy personnel shall compound or prepare drug formulations, strengths, dosage forms, and packages useful in the care of patients.

7.8(2) *Drug formulary.* The pharmacist in charge shall maintain a current formulary of drug products approved for use in the institution and shall be responsible for specifications for those drug products and for selecting their source of supply.

7.8(3) *Medication orders.* Except as provided in subrule 7.8(14), a pharmacist shall receive a copy of the original medication order for review except when the prescriber directly enters the medication order into an electronic medical record system or when the prescriber issues a verbal medication order directly to a registered nurse or pharmacist who then enters the order into an electronic medical record system. If an individual other than the prescriber enters a medication order into an electronic medical record system, the pharmacist shall review and verify the entry against the original order before the drug is dispensed except for emergency use, when the pharmacy is closed, or when the original order is a verbal order from the prescriber to the registered nurse or pharmacist, or as provided in rule 7.7(155A). When the pharmacy is closed, a registered nurse or pharmacist may enter a medication order into an electronic medical record system for the purpose of creating an electronic medication administration record and a pharmacist shall verify the entry against the original medication order as soon as practicable. Hospitalwide and pharmacy stand-alone computer systems shall be secure against unauthorized entry. The use of abbreviations and chemical symbols on medication orders shall be discouraged but, if used, shall be limited to abbreviations and chemical symbols approved by the appropriate patient care committee.

7.8(4) *Stop order.* A written policy or other system concerning stop orders shall be established to ensure that medication orders are not inappropriately continued.

7.8(5) *Emergency drug supplies and floor stock.* Supplies of drugs for use in medical emergencies shall be immediately available at each nursing unit or service area as specified in policies and procedures. Authorized stocks shall be periodically reviewed in a multidisciplinary manner. All drug storage areas

within the hospital shall be routinely inspected to ensure that no outdated or unusable items are present and that all stock items are properly labeled and stored.

7.8(6) *Disaster services.* The pharmacy shall be prepared to provide drugs and pharmaceutical services in the event of a disaster affecting the availability of drugs or internal access to drugs or access to the pharmacy.

7.8(7) *Drugs brought into the institution.* The pharmacist in charge shall determine those circumstances when patient-owned drugs brought into the institution may be administered to a hospital patient and shall establish policies and procedures governing the use and security of drugs brought into the institution. Procedures shall address identification of the drug and methods for ensuring the integrity of the product prior to permitting its use by the patient. The use of patient-owned drugs shall be minimized to the greatest extent possible.

7.8(8) *Samples.* The use of drug samples within the institution shall be eliminated to the extent possible. Sample use is prohibited for hospital inpatient use. If the use of drug samples is permitted for hospital outpatients, that use of samples shall be controlled and the samples shall be distributed through the pharmacy or through a process developed in cooperation with the pharmacy and the institution's appropriate patient care committee, subject to oversight by the pharmacy.

7.8(9) *Investigational drugs.* If investigational drugs are used in the institution:

a. A pharmacist shall be a member of the institutional review board.

b. The pharmacy shall be responsible, in cooperation with the principal investigator, for providing information about investigational drugs used in the institution and for the distribution and control of those drugs.

7.8(10) *Hazardous drugs and chemicals.* The pharmacist, in cooperation with other hospital staff, shall establish policies and procedures for handling drugs and chemicals that are known occupational hazards. The procedures shall maintain the integrity of the drug or chemical and protect hospital personnel.

7.8(11) *Leave meds.* Labeling of prescription drugs for a patient on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing pharmacy shall be responsible for packaging and labeling leave meds in compliance with this subrule.

7.8(12) *Discharge meds.* Drugs authorized for a patient being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the patient removes those drugs from the facility premises. The dispensing pharmacy shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

7.8(13) *Own-use outpatient prescriptions.* If the hospital pharmacy dispenses own-use outpatient prescriptions, the pharmacy shall comply with all requirements of 657—Chapter 6 except rule 657—6.1(155A).

7.8(14) *Influenza and pneumococcal vaccines.* As authorized by federal law, a written or verbal patient-specific medication administration order shall not be required prior to administration to an adult patient of influenza and pneumococcal polysaccharide vaccines pursuant to physician-approved hospital policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's medical record.

[**ARC 8170B**, IAB 9/23/09, effective 10/28/09]

657—7.9(124,155A) Drug information. The pharmacy is responsible for providing the institution's staff and patients with accurate, comprehensive information about drugs and their use and shall serve as its center for drug information.

7.9(1) *Staff education.* The pharmacist shall keep the institution's staff well informed about the drugs used in the institution and their various dosage forms and packagings.

7.9(2) *Patient education.* The pharmacist shall help ensure that all patients are given adequate information about the drugs that they receive. This is particularly important for ambulatory, home care, and discharged patients. These patient education activities shall be coordinated with the nursing and medical staffs and patient education department, if any.

657—7.10(124,155A) Ensuring rational drug therapy. An important aspect of pharmaceutical services is that of maximizing rational drug use. The pharmacist, in concert with the medical staff, shall develop policies and procedures for ensuring the quality of drug therapy.

7.10(1) *Patient profile.* Sufficient patient information shall be collected, maintained, and reviewed by the pharmacist to ensure meaningful and effective participation in patient care. This requires that a drug profile be maintained for each patient receiving care at the hospital. A pharmacist-conducted drug history from patients may be useful in this regard.

a. Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice.

b. The pharmacist shall review each patient's current drug regimen and directly communicate any suggested changes to the prescriber.

7.10(2) *Adverse drug events.* The pharmacist, in cooperation with the appropriate patient care committee, shall develop a mechanism for the reporting and review, by the committee or other appropriate medical group, of adverse drug events. The pharmacist shall be informed of all reported adverse drug events occurring in the facility. Adverse drug events include but need not be limited to adverse drug reactions and medication errors.

657—7.11 Reserved.

657—7.12(124,126,155A) Drugs dispensed to patients as a result of an emergency room visit. In those facilities with 24-hour pharmacy services, only a pharmacist or prescribing practitioner may dispense any drugs to an outpatient, including emergency department patients. In those facilities without 24-hour pharmacy services, or in those facilities without outpatient pharmacy services or when the facility's outpatient pharmacy is closed, the following procedures shall be observed in dispensing drugs:

7.12(1) *Patients examined in emergency room.* Drugs shall be dispensed only to patients who have been examined in the emergency room.

7.12(2) *Accountability.* Drugs shall be dispensed only in accordance with the system of control and accountability for drugs administered or dispensed from the emergency room.

a. The system shall be developed and supervised by the pharmacist in charge and the facility's emergency department committee, or a similar group or person responsible for policy in that department.

b. The system shall identify drugs of the nature and type to meet the immediate needs of emergency room patients.

c. Controlled substances maintained in the emergency room are kept for use by, or at the direction of, prescribers in the emergency room. In order to receive a controlled substance, a patient must be examined in the emergency room by a prescriber who shall determine the need for the drug. It is not permissible under state and federal requirements for a prescriber to see a patient outside the emergency room setting, or talk to the patient on the telephone, and then proceed to call the emergency room and order the administration of a stocked controlled substance upon the patient's arrival at the emergency room. A prescriber may authorize, without again examining the patient, the administration of additional doses of a previously authorized drug to a patient presenting to the emergency department within 24 hours of the patient's examination and treatment in the emergency department.

d. In an emergency situation when a health care practitioner authorized to prescribe controlled substances is not available on site and regardless of the provisions of paragraph *"c,"* the emergency room nurse may examine the patient in the emergency room and contact the on-call prescriber. The on-call prescriber may then authorize the nurse to administer a controlled substance to the patient pending the arrival of the prescriber. As soon as possible, the prescriber shall examine the patient in the emergency room and determine the patient's further treatment needs.

e. The pharmacist in charge is responsible for maintaining accurate records of dispensing of drugs from the emergency room, and for ensuring the accuracy of prepackaged drugs and the complete and accurate labeling of prepackaged drugs pursuant to subrule 7.12(3).

f. Except as provided in subrule 7.12(6), a practitioner who authorizes dispensing to a patient of a prescription drug from the emergency department drug supply is responsible for the accuracy of the dispensed drug and for the accurate completion of label information pursuant to subrule 7.12(4).

7.12(3) *Prepackaging.* Except as provided in subrule 7.12(6), drugs dispensed in greater than a 24-hour supply may be dispensed only in prepackaged quantities not to exceed a 72-hour supply or the minimum prepackaged quantity in suitable containers. Prepackaged drugs shall be prepared pursuant to the requirements of 657—22.3(126). Drugs dispensed pursuant to this subrule shall be appropriately labeled as required in subrule 7.12(4), including necessary auxiliary labels.

7.12(4) *Labeling.* Except as provided in subrule 7.12(6), at the time of delivery of the drug, the practitioner shall appropriately complete the label, such that the dispensing container bears a label with at least the following information:

a. Name and address of the hospital;

b. Date dispensed;

c. Name of prescriber;

d. Name of patient;

e. Directions for use;

f. Name and strength of drug.

7.12(5) *Delivery of drug to patient.* Except as provided in subrule 7.12(6), the practitioner, or a licensed nurse under the supervision of the practitioner, shall give the appropriately labeled, prepackaged drug to the patient or patient's caregiver. The practitioner, or a licensed nurse under the supervision of the practitioner, shall explain the correct use of the drug and shall explain to the patient that the dispensing is for an emergency or starter supply of the drug. If additional quantities of the drug are required to complete the needed course of treatment, the prescriber shall provide the patient with a prescription for the additional quantities.

7.12(6) *Use of InstyMeds dispensing system.* A hospital located in an area of the state where 24-hour outpatient pharmacy services are not available within 15 miles of the hospital may implement the InstyMeds dispensing system in the hospital emergency department only as provided by this subrule.

a. Access to the dispensing machine for the purposes of stocking, inventory, and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns.

b. The InstyMeds dispensing system shall be used only in the hospital emergency department for the benefit of patients examined or treated in the emergency department.

c. The dispensing machine shall be located in a secure and professionally appropriate environment.

d. The stock of drugs maintained and dispensed utilizing the InstyMeds dispensing system shall be limited to acute care drugs provided in appropriate quantities for a 72-hour supply or the minimum commercially available package size, except that antimicrobials may be dispensed in a quantity to provide the full course of therapy.

e. Drugs dispensed utilizing the InstyMeds dispensing system shall be appropriately labeled as provided in 657—subrule 6.10(1), paragraphs *"a"* through *"g."*

f. Prior to authorizing the dispensing of a drug utilizing the InstyMeds dispensing system, the prescriber shall offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice.

g. When appropriate for an acute condition, the prescriber shall provide to the patient or the patient's agent a prescription for the remainder of drug therapy beyond the supply available utilizing the InstyMeds dispensing system. During consultation with the patient or the patient's agent, the prescriber shall clearly explain the appropriate use of the drug supplied, the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice, and the need to complete the full course of drug therapy.

h. The pharmacy shall, in conjunction with the hospital emergency department, implement policies and procedures to ensure that a patient utilizing the InstyMeds dispensing system has been positively identified.

i. The hospital pharmacist shall review the printout of drugs provided utilizing the InstyMeds dispensing system within 24 hours unless the pharmacy is closed, in which case the printout shall be reviewed during the first day the pharmacy is open following the provision of the drugs. The purpose of the review is to identify any dispensing errors, to determine dosage appropriateness, and to complete a retrospective drug use review of any antimicrobials dispensed in a quantity greater than a 72-hour supply. Any discrepancies found shall be addressed by the pharmacy's continuous quality improvement program.

657—7.13(124,155A) Records. Every inventory or other record required to be kept under this chapter or other board rules or under Iowa Code chapters 124 and 155A shall be kept by the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record unless a longer retention period is specified for the particular inventory or record.

7.13(1) *Medication order information.* Each original medication order contained in inpatient records shall bear the following information:

a. Patient name and identification number;

b. Drug name, strength, and dosage form;

c. Directions for use;

d. Date ordered;

e. Practitioner's signature or electronic signature or that of the practitioner's authorized agent.

7.13(2) *Medication order maintained.* The original medication order shall be maintained with the medication administration record in the medical records of the patient following discharge.

7.13(3) *Documentation of drug administration.* Each dose of medication administered shall be properly recorded in the patient's medical record.

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 126.10, 126.11, 155A.6, 155A.13, 155A.27, 155A.28, 155A.31, and 155A.33 through 155A.36.

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◊ Two or more ARCs

CHAPTER 8
UNIVERSAL PRACTICE STANDARDS
[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 6]

657—8.1(155A) Purpose and scope. The requirements of these rules apply to all Iowa-licensed pharmacists and to all pharmacies providing the services addressed in this chapter to patients in Iowa and are in addition to rules of the board relating to specific types of pharmacy licenses issued by the board.

657—8.2(155A) Pharmaceutical care. Pharmaceutical care is a comprehensive, patient-centered, outcomes-oriented pharmacy practice in which the pharmacist accepts responsibility for assisting the prescriber and the patient in optimizing the patient's drug therapy plan and works to promote health, to prevent disease, and to optimize drug therapy. Pharmaceutical care does not include the prescribing of drugs without the consent of the prescribing practitioner.

8.2(1) *Drug therapy problems.* In providing pharmaceutical care, the pharmacist shall strive to identify, resolve, and prevent drug therapy problems.

8.2(2) *Drug therapy plan.* In providing pharmaceutical care, the pharmacist shall access and evaluate patient-specific information, identify drug therapy problems, and utilize that information in a documented plan of therapy that assists the patient or the patient's caregiver in achieving optimal drug therapy. In concert with the patient, the patient's prescribing practitioner, and the patient's other health care providers, the pharmacist shall assess, monitor, and suggest modifications of the plan as appropriate.

8.2(3) *Eligibility.* Any Iowa-licensed pharmacist may practice pharmaceutical care.

657—8.3(155A) Responsibility.

8.3(1) *Pharmacy operations.* The pharmacy and the pharmacist in charge share responsibility for ensuring that all operations of the pharmacy are in compliance with federal and state laws, rules, and regulations relating to pharmacy operations and the practice of pharmacy.

8.3(2) *Practice functions.* The pharmacist is responsible for all functions performed in the practice of pharmacy. The pharmacist maintains responsibility for any and all delegated functions including functions delegated to pharmacist-interns, pharmacy technicians, and other supportive personnel.

8.3(3) *Pharmacist-documented verification.* The pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.

657—8.4(155A) Pharmacist identification.

8.4(1) *Display of pharmacist license.* During any period the pharmacist is working in a pharmacy, each pharmacist shall display, in a position visible to the public, an original license to practice pharmacy. A current license renewal certificate, which may be a photocopy of an original renewal certificate, shall be displayed with the original license.

8.4(2) *Identification codes.* A permanent log of the initials or codes identifying by name each dispensing pharmacist, pharmacist-intern, and pharmacy technician shall be maintained for a minimum of two years and shall be available for inspection and copying by the board or its representative. The initials or identification code shall be unique to the individual to ensure that each pharmacist, pharmacist-intern, and pharmacy technician can be identified.

8.4(3) *Temporary or intermittent pharmacy staff.* The pharmacy shall maintain a log of all pharmacists, pharmacist-interns, and pharmacy technicians who have worked at that pharmacy and who are not regularly staffed at that pharmacy. Such log shall include the dates and shifts worked by each pharmacist, pharmacist-intern, and pharmacy technician and shall be available for inspection and copying by the board or its representative for a minimum of two years following the date of the entry.

8.4(4) *Identification badge.* A pharmacist shall wear a visible identification badge while on duty that clearly identifies the person as a pharmacist and includes at least the pharmacist's first name.

657—8.5(155A) Environment and equipment requirements. There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy. Space and equipment in an amount and type to provide secure, environmentally controlled storage of drugs shall be available.

8.5(1) *Refrigeration.* The pharmacy shall maintain one or more refrigeration units. The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration, and a thermometer shall be maintained in the refrigerator to verify the temperature.

8.5(2) *Sink.* The pharmacy shall have a sink with hot and cold running water located within the pharmacy department and available to all pharmacy personnel; the sink shall be maintained in a sanitary condition.

8.5(3) *Secure barrier.* The pharmacy department shall be surrounded by a physical barrier capable of being securely locked to prevent entry when the department is closed. A secure barrier may be constructed of other than a solid material with a continuous surface if the openings in the material are not large enough to permit removal of items from the pharmacy department by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The plans and specifications of the barrier shall be submitted to the board for approval prior to the start of construction. The board may also require on-site inspection of the facility or pharmacy department prior to the pharmacy's opening or relocation. The pharmacy department shall be closed and secured in the absence of the pharmacist except as provided in rule 657—6.7(124,155A) or 657—7.6(124,155A).

8.5(4) *Orderly and clean.* The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be in good operating condition and maintained in a sanitary manner.

8.5(5) *Light and ventilation.* The pharmacy shall be properly lighted and ventilated.

8.5(6) *Temperature and humidity.* The temperature and humidity of the pharmacy shall be maintained within a range compatible with the proper storage of drugs.

8.5(7) *Other equipment.* The pharmacist in charge shall ensure the availability of any other equipment necessary for the particular practice of pharmacy and to meet the needs of the patients served by the pharmacy.

8.5(8) *Bulk counting machines.* Unless bar-code scanning is required and utilized to verify the identity of each stock container of drugs utilized to restock a counting machine cell or bin, a pharmacist shall verify the accuracy of the drugs to be restocked prior to filling the counting machine cell or bin. A record identifying the individual who verified the drugs to be restocked, the individual who restocked the counting machine cell or bin, and the date shall be maintained. The pharmacy shall have a method to calibrate and verify the accuracy of the counting device and shall, at least quarterly, verify the accuracy of the device and maintain a dated record identifying the individual who performed the quarterly verification.

657—8.6(155A) Health of personnel. Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug dispensing, preparation, compounding, or storage areas. Any person shown, either by medical examination or pharmacist determination, to have an apparent illness or open lesions that may adversely affect the quality or safety of a drug product or another individual shall be excluded from direct contact with components, bulk drug substances, drug product containers, closures, in-process materials, drug products, and patients until the condition is corrected or determined by competent medical personnel not to jeopardize the quality or safety of drug products or patients. All personnel who normally assist the pharmacist shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products or may pose a health or safety risk to others.

657—8.7(155A) Procurement, storage, and recall of drugs and devices.

8.7(1) *Source.* Procurement of prescription drugs and devices shall be from a drug wholesaler licensed by the board to distribute to Iowa pharmacies or, on a limited basis, from another licensed pharmacy or licensed practitioner located in the United States.

8.7(2) *Sufficient stock.* A pharmacy shall maintain sufficient stock of drugs and devices to fulfill the foreseeable needs of the patients served by the pharmacy.

8.7(3) *Manner of storage.* Drugs and devices shall be stored in a manner to protect their identity and integrity.

8.7(4) *Storage temperatures.* All drugs and devices shall be stored at the proper temperature, as defined by the following terms:

a. "Controlled room temperature" means temperature maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit);

b. "Cool" means temperature between 8 degrees and 15 degrees Celsius (46 degrees and 59 degrees Fahrenheit). Drugs and devices may be stored in a refrigerator unless otherwise specified on the labeling;

c. "Refrigerate" means temperature maintained thermostatically between 2 degrees and 8 degrees Celsius (36 degrees and 46 degrees Fahrenheit); and

d. "Freeze" means temperature maintained thermostatically between -20 degrees and -10 degrees Celsius (-4 degrees and 14 degrees Fahrenheit).

8.7(5) *Product recall.* There shall be a system for removing from use, including unit dose, any drugs and devices subjected to a product recall.

657—8.8(124,155A) Out-of-date drugs or devices. Any drug or device bearing an expiration date shall not be dispensed for use beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are properly disposed of.

657—8.9(124,155A) Records. Every inventory or other record required to be maintained by a pharmacy pursuant to board rules or Iowa Code chapters 124 and 155A shall be maintained and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record unless a longer retention period is specified for the particular record or inventory. The following records shall be maintained for at least two years.

8.9(1) *Drug supplier invoices.* All pharmacies shall maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the controlled substances by the pharmacist or other responsible individual is clearly recorded.

8.9(2) *Drug supplier credits.* All pharmacies shall maintain supplier credit memos for controlled substances and prescription drugs.

657—8.10 Reserved.

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

8.11(1) *Misrepresentative deeds.* A pharmacist 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. A pharmacist shall not accept professional employment or share or receive compensation in any form arising out of, or incidental to, the pharmacist's professional activities from a prescriber of prescription drugs or any other person or corporation in which one or more such prescribers have a proprietary or beneficial interest sufficient to permit them to directly or indirectly exercise supervision or control over the pharmacist in the pharmacist's professional responsibilities and duties or over the pharmacy wherein the pharmacist practices.

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.

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

8.11(3) *Lease agreements.* A pharmacist shall not lease space for a pharmacy under any of the following conditions:

a. From a prescriber of prescription drugs or a group, corporation, association, or organization of such prescribers on a percentage of income basis;

b. From a group, corporation, association, or organization in which prescribers have majority control or have directly or indirectly a majority beneficial or proprietary interest on a percentage of income basis; or

c. If the rent is not reasonable according to commonly accepted standards of the community in which the pharmacy will be located.

8.11(4) *Nonconformance with law.* A pharmacist 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 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) *Discrimination.* It is unethical to unlawfully discriminate between patients or groups of patients for reasons of religion, race, creed, color, gender, gender identity, sexual orientation, marital status, age, national origin, physical or mental disability, or disease state when providing pharmaceutical services.

8.11(7) *Claims of professional superiority.* A pharmacist shall not make a claim, assertion, or inference of professional superiority in the practice of pharmacy which cannot be substantiated, or claim an unusual, unsubstantiated capacity to supply a drug or professional service to the community.

8.11(8) *Unprofessional conduct or behavior.* A pharmacist shall not exhibit unprofessional behavior in connection with the practice of pharmacy or refuse to provide reasonable information or answer reasonable questions for the benefit of the patient. Unprofessional behavior shall include, but not be limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.

657—8.12(126,147) Advertising. Prescription drug price and nonprice information may be provided to the public by a pharmacy so long as the information is not false or misleading and is not in violation of any federal or state laws applicable to the advertisement of such articles generally and if all of the following conditions are met:

1. All charges for services to the consumer must be stated.
2. The effective dates for the prices listed shall be stated.
3. No reference shall be made to controlled substances listed in Schedules II through V of the latest revision of the Iowa uniform controlled substances Act and the rules of the Iowa board of pharmacy.

657—8.13(135C,155A) Personnel histories. Pursuant to the requirements of Iowa Code section 135C.33, the provisions of this rule shall apply to any pharmacy employing any person to provide patient care services in a patient's home. For the purposes of this rule, "employed by the pharmacy" shall include any individual who is paid to provide treatment or services to any patient in the patient's home, whether the individual is paid by the pharmacy or by any other entity such as a corporation, a temporary staffing agency, or an independent contractor. Specifically excluded from the requirements of this rule are individuals such as delivery persons or couriers who do not enter the patient's home for the purpose of instructing the patient or the patient's caregiver in the use or maintenance of the equipment, device, or drug being delivered, or who do not enter the patient's home for the purpose of setting up or servicing the equipment, device, or drug used to treat the patient in the patient's home.

8.13(1) *Applicant acknowledgment.* The pharmacy shall ask the following question of each person seeking employment in a position that will provide in-home services: "Do you have a record of founded child or dependent adult abuse or have you ever been convicted of a crime, in this state or any other state?" The applicant shall also be informed that a criminal history and dependent adult abuse record check will be conducted. The applicant shall indicate, by signed acknowledgment, that the applicant has been informed that such record checks will be conducted.

8.13(2) *Criminal history check.* Prior to the employment of any person to provide in-home services as described by this rule, the pharmacy shall submit to the department of public safety a form specified by the department of public safety and receive the results of a criminal history check.

8.13(3) *Abuse history checks.* Prior to the employment of any person to provide in-home services as described by this rule, the pharmacy shall submit to the department of human services a form specified by the department of human services and receive the results of a dependent adult abuse record check. The pharmacy may submit to the department of human services a form specified by the department of human services to request a child abuse history check.

a. A person who has a criminal record, founded dependent adult abuse report, or founded child abuse report shall not be employed by a pharmacy to provide in-home services unless the department of human services has evaluated the crime or founded abuse report, has concluded that the crime or founded abuse does not merit prohibition from such employment, and has notified the pharmacy that the person may be employed to provide in-home services.

b. The pharmacy shall keep copies of all record checks and evaluations for a minimum of two years following receipt of the record or for a minimum of two years after the individual is no longer employed by the pharmacy, whichever is greater.

657—8.14(155A) Training and utilization of pharmacy technicians. All Iowa-licensed pharmacies utilizing pharmacy technicians shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy technicians appropriate to the practice of pharmacy at that licensed location. Pharmacy policies shall specify the frequency of review. Technician training shall be documented and maintained by the pharmacy for the duration of employment. Policies and procedures and documentation of technician training shall be available for inspection by the board or an agent of the board.

657—8.15(155A) Delivery of prescription drugs and devices. Prescription drug orders, prescription devices, and completed prescription drug containers may be delivered, in compliance with all laws, rules, and regulations relating to the practice of pharmacy, to patients at any place of business licensed as a pharmacy.

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).

8.15(2) *Policies and procedures required.* Every pharmacy shipping or otherwise delivering prescription drugs or devices to Iowa patients shall develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements as defined by subrule 8.7(4).

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09]

657—8.16(124,155A) Confidential information.

8.16(1) *Definition.* "Confidential information" means information accessed or maintained by the pharmacy in the patient's records which contains personally identifiable information that could be used to identify the patient. This includes but is not limited to patient name, address, telephone number, and social security number; prescriber name and address; and prescription and drug or device information such as therapeutic effect, diagnosis, allergies, disease state, pharmaceutical services rendered, medical information, and drug interactions, regardless of whether such information is communicated to or from the patient, is in the form of paper, is preserved on microfilm, or is stored on electronic media.

8.16(2) *Release of confidential information.* Confidential information in the patient record may be released only as follows:

a. Pursuant to the express written authorization of the patient or the order or direction of a court.

b. To the patient or the patient's authorized representative.

c. To the prescriber or other licensed practitioner then caring for the patient.

d. To another licensed pharmacist when the best interests of the patient require such release.

e. To the board or its representative or to such other persons or governmental agencies duly authorized by law to receive such information.

A pharmacist shall utilize the resources available to determine, in the professional judgment of the pharmacist, that any persons requesting confidential patient information pursuant to this rule are entitled to receive that information.

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.

8.16(4) *System security and safeguards.* To maintain the integrity and confidentiality of patient records and prescription drug orders, any system or computer utilized shall have adequate security including system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescription drug orders.

8.16(5) *Record disposal.* Disposal of any materials containing or including patient-specific or confidential information shall be conducted in a manner to preserve patient confidentiality.

657—8.17 and **8.18** Reserved.

657—8.19(124,126,155A) Manner of issuance of a prescription drug or medication order. A prescription drug order or medication order may be transmitted from a prescriber to a pharmacy in written form, orally including telephone voice communication, or by electronic transmission in accordance with applicable federal and state laws and rules. Any prescription drug order or medication order provided to a patient in written or printed form shall include the original, handwritten signature of the prescriber except as provided in rule 657—21.7(124,155A).

8.19(1) *Verification.* The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of any prescription drug order or medication order consistent with federal and state laws and rules. In exercising professional judgment, the prescribing practitioner and the pharmacist shall take adequate measures to guard against the diversion of prescription drugs and controlled substances through prescription forgeries.

8.19(2) *Transmitting agent.* The prescribing practitioner may authorize an agent to transmit to the pharmacy a prescription drug order or medication order orally or by electronic transmission provided that the name of the transmitting agent is included in the order.

a. New order. A new written or electronically prepared and transmitted prescription drug or medication order shall be manually or electronically signed by the prescriber. If transmitted by the prescriber's agent, the name and title of the transmitting agent shall be included in the order.

b. Refill order or renewal order. An authorization to refill a prescription drug or medication order, or to renew or continue an existing drug therapy, may be transmitted to a pharmacist through oral communication, in writing, or by electronic transmission initiated by or directed by the prescriber.

(1) If the transmission is completed by the prescriber's agent and the name and title of the transmitting agent is included in the order, the prescriber's signature is not required on the fax or alternate electronic transmission.

(2) If the order differs in any manner from the original order, such as a change of the drug strength, dosage form, or directions for use, the prescriber shall sign the order as provided by paragraph *"a."*

8.19(3) *Receiving agent.* Regardless of the means of transmission to a pharmacy, only a pharmacist, a pharmacist-intern, or a pharmacy technician shall be authorized to receive a prescription drug or medication order from a practitioner or the practitioner's agent.

8.19(4) *Legitimate purpose.* The pharmacist shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner acting in the usual course of the practitioner's professional practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation and without a valid preexisting patient-practitioner relationship.

8.19(5) *Refills.* A prescription for a prescription drug or device that is not a controlled substance may authorize no more than 12 refills within 18 months following the date on which the prescription is issued. A refill is one or more dispensings of a prescription drug or device that results in the patient's receipt of the quantity authorized by the prescriber for a single fill as indicated on the prescription drug order.

[**ARC 8171B**, IAB 9/23/09, effective 10/28/09]

657—8.20(155A) Valid prescriber/patient relationship. Prescription drug orders and medication orders shall be valid as long as a prescriber/patient relationship exists. Once the prescriber/patient

relationship is broken and the prescriber is no longer available to treat the patient or oversee the patient's use of a prescription drug, the order loses its validity and the pharmacist, on becoming aware of the situation, shall cancel the order and any remaining refills. The pharmacist shall, however, exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the prescribed drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new order can be issued.

657—8.21(155A) Prospective drug use review. For purposes of promoting therapeutic appropriateness and ensuring rational drug therapy, a pharmacist shall review the patient record, information obtained from the patient, and each prescription drug or medication order to identify:

1. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse;
8. Drug-prescriber contraindications.

Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem and shall, if necessary, include consultation with the prescriber. The review and assessment of patient records shall not be delegated to staff assistants but may be delegated to registered pharmacist-interns under the direct supervision of the pharmacist.

657—8.22 to **8.25** Reserved.

657—8.26(155A) Continuous quality improvement program. Each pharmacy licensed to provide pharmaceutical services to patients in Iowa shall implement or participate in a continuous quality improvement program or CQI program. The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and the quality of patient care. A pharmacy that participates as an active member of a hospital or corporate CQI program that meets the objectives of this rule shall not be required to implement a new program pursuant to this rule.

8.26(1) *Reportable program events.* For purposes of this rule, a reportable program event or program event means a preventable medication error resulting in the incorrect dispensing of a prescribed drug received by or administered to the patient and includes but is not necessarily limited to:

a. An incorrect drug;
b. An incorrect drug strength;
c. An incorrect dosage form;
d. A drug received by the wrong patient;
e. Inadequate or incorrect packaging, labeling, or directions; or
f. Any incident related to a prescription dispensed to a patient that results in or has the potential to result in serious harm to the patient.

8.26(2) *Responsibility.* The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of this rule. The pharmacist in charge may delegate program administration and monitoring, but the pharmacist in charge maintains ultimate responsibility for the validity and consistency of program activities.

8.26(3) *Policies and procedures.* Each pharmacy shall develop, implement, and adhere to written policies and procedures for the operation and management of the pharmacy's CQI program. A copy of the pharmacy's CQI program description and policies and procedures shall be maintained and readily available to all pharmacy personnel. The policies and procedures shall address, at a minimum, a planned process to:

a. Train all pharmacy personnel in relevant phases of the CQI program;

b. Identify and document reportable program events;

c. Minimize the impact of reportable program events on patients;

d. Analyze data collected to assess the causes and any contributing factors relating to reportable program events;

e. Use the findings to formulate an appropriate response and to develop pharmacy systems and workflow processes designed to prevent and reduce reportable program events; and

f. Periodically, but at least annually, meet with appropriate pharmacy personnel to review findings and inform personnel of changes that have been made to pharmacy policies, procedures, systems, or processes as a result of CQI program findings.

8.26(4) *Event discovery and notification.* As provided by the procedures of the CQI program, the pharmacist in charge or appropriate designee shall be informed of and review all reported and documented program events. All pharmacy personnel shall be trained to immediately inform the pharmacist on duty of any discovered or suspected program event. When the pharmacist on duty determines that a reportable program event has occurred, the pharmacist shall ensure that all reasonably necessary steps are taken to remedy any problems or potential problems for the patient and that those steps are documented. Necessary steps include, but are not limited to, the following:

a. Notifying the patient or the patient's caregiver and the prescriber or other members of the patient's health care team as warranted;

b. Identifying and communicating directions or processes for correcting the error; and

c. Communicating instructions for minimizing any negative impact on the patient.

8.26(5) *CQI program records.* All CQI program records shall be maintained on site at the pharmacy or shall be accessible at the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the record. When a reportable program event occurs or is suspected to have occurred, the program event shall be documented in a written or electronic storage record created solely for that purpose. Records of program events shall be maintained in an orderly manner and shall be filed chronologically by date of discovery.

a. The program event shall initially be documented as soon as practicable by the staff member who discovers the event or is informed of the event.

b. Program event documentation shall include a description of the event that provides sufficient information to permit categorization and analysis of the event and shall include:

(1) The date and time the program event was discovered and the name of the staff person who discovered the event; and

(2) The names of the individuals recording and reviewing or analyzing the program event information.

8.26(6) *Program event analysis and response.* The pharmacist in charge or designee shall review each reportable program event and determine if follow-up is necessary. When appropriate, information and data collected and documented shall be analyzed, individually and collectively, to assess the cause and any factors contributing to the program event. The analysis may include, but is not limited to, the following:

a. A consideration of the effects on the quality of the pharmacy system related to workflow processes, technology utilization and support, personnel training, and both professional and technical staffing levels;

b. Any recommendations for remedial changes to pharmacy policies, procedures, systems, or processes; and

c. The development of a set of indicators that a pharmacy will utilize to measure its program standards over a designated period of time.

657—8.27 to **8.29** Reserved.

657—8.30(126,155A) Sterile products. Rescinded IAB 6/6/07, effective 7/11/07.

657—8.31 Reserved.

657—8.32(124,155A) Individuals qualified to administer. The board designates the following as qualified individuals to whom a practitioner may delegate the administration of prescription drugs. Any person specifically authorized under pertinent sections of the Iowa Code to administer prescription drugs shall construe nothing in this rule to limit that authority.

1. Persons who have successfully completed a medication administration course.
2. Licensed pharmacists.

657—8.33(147,155A) Supervision of pharmacists who administer adult immunizations. A physician may prescribe via written protocol adult immunizations for influenza and pneumococcal vaccines for administration by an authorized pharmacist if the physician meets these requirements for supervising the pharmacist.

8.33(1) *Definitions.*

a. "Authorized pharmacist" means an Iowa-licensed pharmacist who has documented that the pharmacist has successfully completed an organized course of study in a college or school of pharmacy or an Accreditation Council for Pharmacy Education (ACPE)-approved continuing pharmaceutical education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol for health care providers;

(2) Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current Centers for Disease Control and Prevention guidelines, and provides instruction and experiential training in the following content areas:

1. Standards for immunization practices;
2. Basic immunology and vaccine protection;
3. Vaccine-preventable diseases;
4. Recommended immunization schedules;
5. Vaccine storage and management;
6. Informed consent;
7. Physiology and techniques for vaccine administration;
8. Pre- and post-vaccine assessment and counseling;
9. Immunization record management; and
10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

b. "Vaccine" means a specially prepared antigen which, upon administration to a person, will result in immunity and, specifically for the purposes of this rule, shall mean influenza and pneumococcal vaccines.

c. "Written protocol" means a physician's order for one or more patients that contains, at a minimum, the following:

(1) A statement identifying the individual physician authorized to prescribe drugs and responsible for the delegation of administration of adult immunizations for influenza and pneumococcus;

(2) A statement identifying the individual authorized pharmacist;

(3) A statement that forbids an authorized pharmacist from delegating the administration of adult immunizations to anyone other than another authorized pharmacist, a registered pharmacist-intern under the direct personal supervision of the authorized pharmacist, or a registered nurse;

(4) A statement identifying the vaccines that may be administered by an authorized pharmacist, the dosages, and the route of administration;

(5) A statement identifying the activities an authorized pharmacist shall follow in the course of administering adult immunizations, including:

1. Procedures for determining if a patient is eligible to receive the vaccine;
2. Procedures for determining the appropriate scheduling and frequency of drug administration in accordance with applicable guidelines;

3. Procedures for record keeping and long-term record storage including batch or identification numbers;

4. Procedures to follow in case of life-threatening reactions; and

5. Procedures for the pharmacist and patient to follow in case of reactions following administration.

(6) A statement that describes how the authorized pharmacist shall report the administration of adult immunizations, within 30 days, to the physician issuing the written protocols and to the patient's primary care physician if one has been designated by the patient. In case of serious complications, the authorized pharmacist shall notify the physicians within 24 hours and submit a VAERS report to the bureau of immunizations, Iowa department of public health. (VAERS is the Vaccine Advisory Event Reporting System.) A serious complication is one that requires further medical or therapeutic intervention to effectively protect the patient from further risk, morbidity, or mortality.

8.33(2) *Supervision.* A physician who prescribes adult immunizations to an authorized pharmacist for administration shall adequately supervise that pharmacist. Physician supervision shall be considered adequate if the delegating physician:

a. Ensures that the authorized pharmacist is prepared as described in subrule 8.33(1), paragraph *"a"*;

b. Provides a written protocol that is updated at least annually;

c. Is available through direct telecommunication for consultation, assistance, and direction, or provides physician backup to provide these services when the physician supervisor is not available;

d. Is an Iowa-licensed physician who has a working relationship with an authorized pharmacist within the physician's local provider service area.

8.33(3) *Administration of other adult immunizations by pharmacists.* A physician may prescribe, for an individual patient by prescription or medication order, other adult immunizations to be administered by an authorized pharmacist.

This rule is intended to implement Iowa Code sections 147.76, 155A.3, 155A.4, and 272C.3.

657—8.34(155A) Collaborative drug therapy management. An authorized pharmacist may only perform collaborative drug therapy management pursuant to protocol with a physician pursuant to the requirements of this rule. The physician retains the ultimate responsibility for the care of the patient. The pharmacist is responsible for all aspects of drug therapy management performed by the pharmacist.

8.34(1) *Definitions.*

"Authorized pharmacist" means an Iowa-licensed pharmacist whose license is in good standing and who meets the drug therapy management criteria defined in this rule.

"Board" means the board of pharmacy.

"Collaborative drug therapy management" means participation by an authorized pharmacist and a physician in the management of drug therapy pursuant to a written community practice protocol or a written hospital practice protocol.

"Collaborative practice" means that a physician may delegate aspects of drug therapy management for the physician's patients to an authorized pharmacist through a community practice protocol. "Collaborative practice" also means that a P&T committee may authorize hospital pharmacists to perform drug therapy management for inpatients and hospital clinic patients through a hospital practice protocol.

"Community practice protocol" means a written, executed agreement entered into voluntarily between an authorized pharmacist and a physician establishing drug therapy management for one or more of the pharmacist's and physician's patients residing in a community setting. A community practice protocol shall comply with the requirements of subrule 8.34(2).

"Community setting" means a location outside a hospital inpatient, acute care setting or a hospital clinic setting. A community setting may include, but is not limited to, a home, group home, assisted living facility, correctional facility, hospice, or long-term care facility.

"Drug therapy management criteria" means one or more of the following:

1. Graduation from a recognized school or college of pharmacy with a doctor of pharmacy (Pharm.D.) degree;

2. Certification by the Board of Pharmaceutical Specialties (BPS);

3. Certification by the Commission for Certification in Geriatric Pharmacy (CCGP);

4. Successful completion of a National Institute for Standards in Pharmacist Credentialing (NISPC) disease state management examination and credentialing by the NISPC;

5. Successful completion of a pharmacy residency program accredited by the American Society of Health-System Pharmacists (ASHP); or

6. Approval by the board of pharmacy.

"Hospital clinic" means an outpatient care clinic operated and affiliated with a hospital and under the direct authority of the hospital's P&T committee.

"Hospital pharmacist" means an Iowa-licensed pharmacist who meets the requirements for participating in a hospital practice protocol as determined by the hospital's P&T committee.

"Hospital practice protocol" means a written plan, policy, procedure, or agreement that authorizes drug therapy management between hospital pharmacists and physicians within a hospital and the hospital's clinics as developed and determined by the hospital's P&T committee. Such a protocol may apply to all pharmacists and physicians at a hospital or the hospital's clinics or only to those pharmacists and physicians who are specifically recognized. A hospital practice protocol shall comply with the requirements of subrule 8.34(3).

"IBM" means the Iowa board of medicine.

"P&T committee" means a committee of the hospital composed of physicians, pharmacists, and other health professionals that evaluates the clinical use of drugs within the hospital, develops policies for managing drug use and administration in the hospital, and manages the hospital drug formulary system.

"Physician" means a person who is currently licensed in Iowa to practice medicine and surgery, osteopathic medicine and surgery, or osteopathy. A physician who executes a written protocol with an authorized pharmacist shall supervise the pharmacist's activities involved in the overall management of patients receiving medications or disease management services under the protocol. The physician may delegate only drug therapies that are in areas common to the physician's practice.

"Therapeutic interchange" means an authorized exchange of therapeutic alternate drug products in accordance with a previously established and approved written protocol.

8.34(2) *Community practice protocol.*

a. An authorized pharmacist shall engage in collaborative drug therapy management with a physician only under a written protocol that has been identified by topic and has been submitted to the board or a committee authorized by the board. A protocol executed after July 1, 2008, will no longer be required to be submitted to the board; however, written protocols executed or renewed after July 1, 2008, shall be made available upon request of the board or the IBM.

b. The community practice protocol shall include:

(1) The name, signature, date, and contact information for each authorized pharmacist who is a party to the protocol and is eligible to manage the drug therapy of a patient. If more than one authorized pharmacist is a party to the agreement, the pharmacists shall work for a single licensed pharmacy and a principal authorized pharmacist shall be designated in the protocol.

(2) The name, signature, date, and contact information for each physician who may prescribe drugs and is responsible for supervising a patient's drug therapy management. The physician who initiates a protocol shall be considered the main caregiver for the patient respective to that protocol and shall be noted in the protocol as the principal physician.

(3) The name and contact information of the principal physician and the principal authorized pharmacist who are responsible for development, training, administration, and quality assurance of the protocol.

(4) A detailed written protocol pursuant to which the authorized pharmacist will base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol

shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the patient's physician. The protocol shall not authorize the pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the patient's physician for follow-up.

4. Patient activities. The protocol may authorize the pharmacist to monitor specific patient activities.

(5) Procedures for securing the patient's written consent. If the patient's consent is not secured by the physician, the authorized pharmacist shall secure such and notify the patient's physician within 24 hours.

(6) Circumstances that shall cause the authorized pharmacist to initiate communication with the physician including but not limited to the need for new prescription orders and reports of the patient's therapeutic response or adverse reaction.

(7) A detailed statement identifying the specific drugs, laboratory tests, and physical findings upon which the authorized pharmacist shall base drug therapy management decisions.

(8) A provision for the collaborative drug therapy management protocol to be reviewed, updated, and reexecuted or discontinued at least every two years.

(9) A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the physician.

(10) A description of the types of reports the authorized pharmacist is to provide to the physician and the schedule by which the pharmacist is to submit these reports. The schedule shall include a time frame within which a pharmacist shall report any adverse reaction to the physician.

(11) A statement of the medication categories and the type of initiation and modification of drug therapy that the physician authorizes the pharmacist to perform.

(12) A description of the procedures or plan that the pharmacist shall follow if the pharmacist modifies a drug therapy.

(13) Procedures for record keeping, record sharing, and long-term record storage.

(14) Procedures to follow in emergency situations.

(15) A statement that prohibits the authorized pharmacist from delegating drug therapy management to anyone other than another authorized pharmacist who has signed the applicable protocol.

(16) A statement that prohibits a physician from delegating collaborative drug therapy management to any unlicensed or licensed person other than another physician or an authorized pharmacist.

(17) A description of the mechanism for the pharmacist and the physician to communicate with each other and for documentation by the pharmacist of the implementation of collaborative drug therapy.

c. Collaborative drug therapy management is valid only when initiated by a written protocol executed by at least one authorized pharmacist and at least one physician.

d. The collaborative drug therapy protocol must be filed with the board, kept on file in the pharmacy, and be made available upon request of the board or the IBM. After July 1, 2008, protocols shall no longer be filed with the board but shall be maintained in the pharmacy and made available to the board and the IBM upon request.

e. A physician may terminate or amend the collaborative drug therapy management protocol with an authorized pharmacist if the physician notifies, in writing, the pharmacist and the board. Notification shall include the name of the authorized pharmacist, the desired change, and the proposed effective date of the change. After July 1, 2008, the physician shall no longer be required to notify the board of changes in a protocol but the written notification shall be maintained in the pharmacy and made available upon request of the board or the IBM.

f. The physician or pharmacist who initiates a protocol with a patient is responsible for securing a patient's written consent to participate in drug therapy management and for transmitting a copy of the

consent to the other party within 24 hours. The consent shall indicate which protocol is involved. Any variation in the protocol for a specific patient shall be communicated to the other party at the time of securing the patient's consent. The patient's physician shall maintain the patient consent in the patient's medical record.

8.34(3) *Hospital practice protocol.*

a. A hospital's P&T committee shall determine the scope and extent of collaborative drug therapy management practices that may be conducted by the hospital's pharmacists.

b. Collaborative drug therapy management within a hospital setting or the hospital's clinic setting is valid only when approved by the hospital's P&T committee.

c. The hospital practice protocol shall include:

(1) The names or groups of pharmacists and physicians who are authorized by the P&T committee to participate in collaborative drug therapy management.

(2) A plan for development, training, administration, and quality assurance of the protocol.

(3) A detailed written protocol pursuant to which the hospital pharmacist shall base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Medication orders and prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the physician. The protocol shall not authorize the hospital pharmacist to change a Schedule II drug or to initiate a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the hospital pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the hospital pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the physician for follow-up.

(4) Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's physician including but not limited to the need for new medication orders and prescription drug orders and reports of a patient's therapeutic response or adverse reaction.

(5) A statement of the medication categories and the type of initiation and modification of drug therapy that the P&T committee authorizes the hospital pharmacist to perform.

(6) A description of the procedures or plan that the hospital pharmacist shall follow if the hospital pharmacist modifies a drug therapy.

(7) A description of the mechanism for the hospital pharmacist and the patient's physician to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy.

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 working in the pharmacy, and the average number of hours worked by each pharmacist and each pharmacy technician 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 $150.

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 $150. Failure to renew the license before February 1 following expiration shall require payment of the renewal fee and a penalty fee of $250. Failure to renew the license before March 1 following expiration shall require payment of the renewal fee and a penalty fee of $350. Failure to renew the license before April 1 following expiration shall require payment of the renewal fee and a penalty fee of $450 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 $600.

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. 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. 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 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 following the stock sale or transfer.

c. A change of pharmacist in charge shall require completion and submission of the application and fee for new pharmacy license . 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. 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) *Pharmacy closing.* 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. Prior notification 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 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. 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.

c. 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).

d. The license certificate and CSA 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.

e. 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.

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.

These rules are intended to implement Iowa Code sections 124.101, 124.301, 124.306, 124.308, 126.10, 126.11, 126.16, 135C.33, 147.7, 147.55, 147.72, 147.74, 147.76, 155A.2 through 155A.4, 155A.6, 155A.10, 155A.12 through 155A.15, 155A.19, 155A.20, 155A.27 through 155A.29, 155A.32, and 155A.33.

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◊ Two or more ARCs

CHAPTER 9
AUTOMATED MEDICATION DISTRIBUTION SYSTEMS AND TELEPHARMACY SERVICES

657—9.1(155A) Purpose and scope. The purposes of this chapter are to provide standards for the utilization of automated medication distribution systems in the practice of pharmacy and to provide standards for the provision of telepharmacy services to patients in areas of Iowa without local pharmacy services. These rules provide for pharmacy services at a remote dispensing site utilizing an automated pharmacy system that is linked to a managing pharmacy. Both the remote dispensing site and the managing pharmacy shall be located within Iowa and appropriately licensed by the board.

657—9.2(147,155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Automated medication distribution system" or *"AMDS"* includes, but is not limited to, an automated device or series of devices operated by an electronic interface with one or more computers that is used to prepare, package, or dispense specified dosage units of drugs for administration or dispensing to a patient or the ultimate user. "AMDS" includes a device that prepares and packages a drug for unit dose dispensing, that prepares and packages a drug into outpatient prescription vials, and that dispenses prepackaged drugs.

"Automated pharmacy system" means a system that utilizes an automated medication distribution system to monitor and control the dispensing of prescription drugs and that provides for related drug use review and patient counseling via an electronic method that includes the use of linked computer, audio, and video communication technologies between a managing pharmacy and a remote dispensing site.

"Board" means the board of pharmacy.

"Centralized unit dose AMDS" means an AMDS located within the pharmacy department where automated technology is utilized in the dispensing of patient-specific unit dose drugs.

"Component" means any single physical or electronic storage or access device that, in combination with other devices, makes up the AMDS.

"DEA" means the Drug Enforcement Administration of the U.S. Department of Justice.

"Decentralized unit dose AMDS" means an AMDS where automated technology is utilized in the dispensing of unit dose drugs for administration to patients in an institutional setting and drug-dispensing components are maintained within the institution but outside the pharmacy department.

"Drug access" means the physical entry into any component of the AMDS for the purpose of stocking or removing drugs.

"Drug bin" means a compartment in an AMDS component that is designed to contain one specific drug.

"Emergency drugs" means those drugs critical for patient care and approved by the institution's pharmacy and therapeutics committee or equivalent committee. Drugs critical for patient care include drugs requiring administration within minutes or within less time than the pharmacy can be practically expected to respond, such as the administration of naloxone for treatment of an opioid overdose.

"Floor-stock drugs" means those drugs consisting of emergency drugs and controlled substances which are routinely maintained on patient care units and accessible by nursing staff for patient administration.

"Information access" means the entry into a record-keeping component of the AMDS, by electronic or other means, for the purpose of adding, updating, or retrieving any patient record or drug record or data.

"Managing pharmacy" means a licensed community pharmacy providing telepharmacy services at one or more licensed remote dispensing sites.

"Outpatient AMDS" means an AMDS where automated technology is utilized in the dispensing of prescriptions for ambulatory patients and includes an AMDS located at a remote dispensing site.

"Qualified certified pharmacy technician" or *"technician"* means a pharmacy technician registered in good standing with the board who has obtained and maintains current certification by a national technician certification authority approved by the board pursuant to 657—Chapter 3.

"Remote dispensing site" or *"remote site"* means a licensed pharmacy staffed by one or more qualified certified pharmacy technicians at which telepharmacy services are provided through a licensed managing pharmacy.

"Telepharmacy" means the provision of pharmaceutical care services, including the storage and dispensing of prescription drugs, drug regimen review, and patient counseling, at a remote dispensing site using an automated pharmacy system.

657—9.3(147,155A) Pharmacist in charge responsibilities.

9.3(1) *AMDS.* The pharmacist in charge of any pharmacy utilizing an AMDS shall be responsible for the following in addition to other responsibilities assigned under federal and state laws and regulations:

a. Implementing an ongoing quality assurance program which purpose is to monitor and improve performance of each AMDS as provided in rule 9.10(147,155A).

b. Establishing and ensuring compliance with all policies and procedures relating to the AMDS.

c. Assigning, discontinuing, or changing drug and information access to the AMDS.

d. Ensuring that drug access, including access to controlled substances, is in compliance with state and federal regulations.

e. Ensuring that each AMDS component is filled or stocked accurately and in accordance with established, written policies and procedures.

f. Ensuring that each AMDS component is in good working order and performs its designated tasks, including ensuring the correct strength, dosage form, and quantity of the prescribed drug.

g. Ensuring that the AMDS has adequate security safeguards regarding drug access and information access.

h. Ensuring that confidentiality of patient-specific information is maintained.

i. Ensuring that all personnel utilizing or accessing the AMDS or any component of the AMDS have been appropriately trained.

j. Ensuring that the board is provided with written notice at least 30 days prior to an installation, removal, or upgrade that significantly changes the operation of an AMDS. The notice shall include:

(1) The name, address, and license number of the pharmacy;

(2) The location of the automated equipment;

(3) Identification of the pharmacist in charge;

(4) The name, manufacturer, and model of the system;

(5) A description of the change or upgrade, if applicable, and a description of the intended use of the equipment; and

(6) If a new or significantly changed AMDS will be installed or upgraded, a copy of the quality assurance plan.

9.3(2) *Telepharmacy.* The pharmacist in charge of the managing pharmacy shall also serve as the pharmacist in charge of the remote dispensing site. In addition to other responsibilities assigned under federal and state laws and regulations, including the responsibilities identified in rule 657—6.2(155A), the pharmacist in charge shall be responsible for, at a minimum, the following:

a. Submitting for board approval the operational plan for the telepharmacy service, including identification of the managing pharmacy; identification of the remote dispensing site; the names and titles of key personnel at both locations; the quality assurance and improvement plan; policies and procedures as provided in rule 9.11(147,155A); identification of the AMDS as provided in subrule 9.3(1), paragraph *"j"*; justification of the need for the telepharmacy service as provided in subrule 9.5(2); and a copy of the proposed contract between the managing pharmacy and the remote dispensing site.

b. Maintaining all licenses and registrations required of the managing pharmacy and of the remote dispensing site.

c. Ensuring that the practice of telepharmacy performed at a remote dispensing site, including the utilization of an automated pharmacy system and the supervision of one or more qualified certified pharmacy technicians, complies with these rules and other applicable rules of the board.

d. Ensuring that the managing pharmacy and the remote dispensing site have entered into a written contract as provided by subrule 9.5(6).

e. Ensuring that the automated pharmacy system is in good working order and that the AMDS accurately dispenses the correct strength, dosage form, and quantity of the prescribed drug and accurately prints the prescription label, while maintaining appropriate record-keeping and security safeguards.

f. Ensuring that all pharmacists, pharmacist-interns, and pharmacy technicians authorized to engage in telepharmacy services at the managing pharmacy or the remote site maintain current licensure or registration with the board and are trained in the operation of the automated pharmacy system and familiar with policies and procedures relating to the telepharmacy practice.

g. Ensuring that a pharmacist completes and documents monthly inspections of each remote site pursuant to subrule 9.5(8).

657—9.4 Reserved.

657—9.5(124,155A) General requirements for telepharmacy. The pharmacist in charge of the managing pharmacy shall ensure that the managing pharmacy and the remote site have obtained all necessary licenses, registrations, and authorizations prior to engaging in the practice of telepharmacy at the remote dispensing site. Regardless of the fact that both the managing pharmacy and the remote site are required to be licensed, the remote site is considered an extension of the managing pharmacy.

9.5(1) *License requirements.*

a. Managing pharmacy. A managing pharmacy shall maintain a license issued by the board pursuant to 657—8.35(155A). The license shall be a general pharmacy license. A managing pharmacy engaged in the dispensing of controlled substances shall maintain registrations with the DEA and the board.

b. Remote dispensing site. A remote site shall maintain a license issued by the board pursuant to 657—8.35(155A). The application for initial licensure shall include the information identified in subrules 9.5(2) and 9.5(6). The license shall be a limited use pharmacy license. If controlled substances are maintained at or dispensed from the remote site, the remote site shall maintain registrations with the DEA and the board that authorize the stocking and dispensing of controlled substances from the remote site.

9.5(2) *Need for remote dispensing site.* Prior to engaging in the practice of telepharmacy with a remote dispensing site, the managing pharmacy shall demonstrate to the board that there is limited access to pharmacy services in the community where the remote site is located.

a. Information justifying the need for the remote dispensing site shall be submitted to the board with the initial application for licensure of the remote site as a limited use pharmacy.

b. The board shall consider the availability of pharmacists in the community, whether the request is for availability of patient care in a critical access area or is solely for the benefit of the managing pharmacy, whether any benefit to the managing pharmacy will balance the benefit to the patients of the remote dispensing site, the population of the community to be served by the remote site, and the need for the service.

c. The board shall not approve a remote dispensing site if a general pharmacy that dispenses prescription drug orders to outpatients is located within the same community as the proposed remote site or is located within 15 miles of the proposed remote dispensing site.

9.5(3) *Reference library.* A managing pharmacy shall comply with the requirements for a reference library found at 657—6.3(155A); a remote site shall be exempt from complying with the requirements for a reference library.

9.5(4) *Patient notification.* A remote site shall display a sign, easily visible to the public, that informs patients that the location is a remote dispensing site providing telepharmacy services supervised by a pharmacist located in another pharmacy, that identifies the city where the managing pharmacy is located, and that informs patients that a pharmacist is required to speak with the patient over an audiovisual link each time a prescription drug is delivered to the patient at the remote site.

9.5(5) *Environment and equipment.* A managing pharmacy and a remote site shall comply with the requirements for environment and equipment found at 657—8.5(155A) except that a remote site that

does not dispense drugs requiring refrigeration shall be exempt from complying with the requirements of 657—subrule 8.5(1).

9.5(6) *Written contract.* A managing pharmacy and a remote dispensing site, unless jointly owned, shall enter into a written contract that outlines the services to be provided and the responsibilities and accountability of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations.

a. A copy of the contract shall be submitted to the board for approval with the initial application for licensure of the remote site as a limited use pharmacy and at any time there is a substantial change in any of the terms of the contract.

b. The contract shall be maintained by the managing pharmacy and shall be available for inspection or copying by the board or an agent of the board for a minimum of two years following expiration or other termination of the contract.

9.5(7) *Changes relating to remote dispensing site.* Pursuant to the requirements of 657—8.35(155A), a managing pharmacy shall notify the board of a change of name, change of location, change of ownership, change of pharmacist in charge, discontinuance of service, or closure of a remote dispensing site operated by the managing pharmacy. A managing pharmacy shall also notify the board of any change of qualified certified pharmacy technician staffing at a remote dispensing site.

9.5(8) *Monthly inspection.* A pharmacist shall complete and document the monthly inspection of a remote dispensing site. Inspection criteria shall be identified in the policies and procedures for the remote site, and inspection reports shall be maintained and available to the board or an agent of the board for review and copying for a minimum of 12 months from the date of the monthly inspection or until the next board inspection, whichever period is longer.

657—9.6(155A) Duties of pharmacist in telepharmacy practice. The following activities shall be performed only by a pharmacist at the managing pharmacy or at the remote dispensing site. These activities may not be delegated to a pharmacy technician at a remote site.

1. Receiving an oral prescription drug order from a prescriber or the prescriber's agent for dispensing to a patient at the remote site.
2. Interpreting a prescription drug order.
3. Verifying the accuracy of prescription data entry.
4. Interpreting the patient's drug record and conducting a drug use review.
5. Authorizing the AMDS to dispense a prescription drug and print a prescription label at the remote site.
6. Performing the final verification of a dispensed prescription as specified in subrule 9.18(7) to ensure that the prescription drug order has been accurately dispensed as prescribed.
7. Counseling the patient or the patient's caregiver as specified in subrule 9.18(8).
8. Completing and documenting the monthly inspection of the remote site pursuant to subrule 9.5(8).

657—9.7 to **9.9** Reserved.

657—9.10(147,155A) Quality assurance and performance improvement. The goal of any AMDS is the accurate dispensing of drugs. In all dispensing activities, the pharmacy shall strive for 100 percent accuracy. Quality assurance data shall be utilized to monitor and improve systems.

9.10(1) *AMDS.* Pharmacies utilizing an AMDS shall develop a written quality assurance and monitoring plan prior to implementation of the AMDS. The quality assurance plan shall target the preparation, delivery, and verification of AMDS unit contents during fill and refill processes and shall include, but not be limited to, the following:

a. Requiring continuous monitoring of the system.
b. Establishing mechanisms and procedures to test the accuracy of the system.
c. Establishing a protocol for measuring the effectiveness of the system.
d. Requiring the pharmacy to report to the board each recurring error of the system.

9.10(2) *Telepharmacy.* In addition to the requirements of subrule 9.10(1), a managing pharmacy that provides telepharmacy services at a remote dispensing site shall operate according to a written program for quality assurance that includes, but is not limited to, the following:

a. Requiring continuous supervision of the remote dispensing site at all times when the remote site is open to provide telepharmacy services.

b. Requiring a pharmacist at the managing pharmacy to be accessible to respond to inquiries or requests pertaining to drugs that are dispensed by utilizing the automated pharmacy system located at the remote dispensing site.

c. Establishing procedures to test the operation of all aspects of the automated pharmacy system, including all electronic audio and video communication components, at a minimum of every six months and whenever any upgrade or change is made to the system, and to document the testing of each system.

d. Establishing a written plan for recovery from a failure of the automated pharmacy system or any component of the system pursuant to subrule 9.10(3).

9.10(3) *Recovery from failure of the automated pharmacy system.* The written plan for recovery from an event that interrupts the ability of a pharmacist to electronically supervise the automated pharmacy system and the dispensing of drugs at the remote dispensing site shall include, at a minimum, the following:

a. A statement that drugs shall not be dispensed at the remote dispensing site if a pharmacist is not available or able to electronically supervise such dispensing, including the utilization of audio and video communication, or if a pharmacist is not on site at the remote dispensing site to personally dispense the drugs.

b. Procedures for response when the automated pharmacy system is experiencing downtime.

c. Procedures for the maintenance and testing of the written plan for recovery.

d. Procedures for notifying the board and other appropriate agencies or organizations of a disaster affecting the ability of the pharmacy to provide services for an extended period of time, including the date on which the pharmacy expects to recommence services.

9.10(4) *Records.* All records and documentation of quality assurance and monitoring, performance improvement projects, and recovery from system failure shall be maintained by the managing pharmacy and be available for inspection and copying by the board or its representative for a minimum of two years from the date of the record.

657—9.11(147,155A) Policies and procedures. All policies and procedures shall be in writing and shall be maintained in the pharmacy responsible for the AMDS or, if a telepharmacy practice, shall be maintained at both the managing pharmacy and the remote site. All policies and procedures shall be reviewed at least annually and revised as necessary, and the review shall be documented. Additions, deletions, amendments, and other changes to policies and procedures shall be signed or initialed by the pharmacist in charge, shall include the date on which the change was approved, and shall be maintained for a minimum of two years following the date of the change. The policy and procedure manual and retained changes shall be available for inspection and copying by the board or an agent of the board.

9.11(1) *AMDS.* All pharmacies utilizing AMDS shall develop, implement, and adhere to policies and procedures that address, at a minimum, the following:

a. Type of equipment, system components, and location of each system component including:

(1) Name and address of the pharmacy, including identification of the specific location within an institution but outside the pharmacy where any component of the AMDS is being used;

(2) Name and address of any remote dispensing site where a component of the AMDS is being used; and

(3) Manufacturer's name and model of each system component.

b. Drug access and information access procedures.

c. Security and confidentiality of records in compliance with 657—8.16(124,155A) and 657—21.2(124,155A).

d. Description of how each component is being utilized, including processes for dispensing and distributing drugs.

e. Staff education and training.

f. Review, including prospective drug use review, of medication orders and prescriptions in accordance with federal and state laws and regulations.

g. Patient counseling on outpatient prescriptions.

h. Quality assurance and quality improvement.

i. Downtime or system failure procedures.

j. Periodic system maintenance and preventive maintenance.

k. Drug security and control including:

(1) Drug loading, storage, and records.

(2) Drugs removed from system components but not used.

(3) Inventory.

(4) Cross contamination.

(5) Lot number control.

(6) Wasted or discarded drugs.

(7) Controlled substances.

9.11(2) *Telepharmacy.* In addition to other requirements for policies and procedures relating to pharmacy practices and the requirements of subrule 9.11(1) relating to policies and procedures for utilization of the AMDS, pharmacies engaging in telepharmacy shall develop, implement, and adhere to policies and procedures that address, at a minimum, the following:

a. Security, including identification by name of the personnel designated by the pharmacist in charge to have access to drug storage and dispensing areas at the remote dispensing site and to receive drugs delivered to the remote dispensing site.

b. Operation of the automated pharmacy system, including identification by name of the personnel designated by the pharmacist in charge to operate the system from the remote site or from the managing pharmacy, and identification by name of the individuals responsible for daily and periodic testing of the automated pharmacy system.

c. Identification of duties that may be performed only by a pharmacist.

d. Sanitation.

e. Storage of drugs and devices at the remote site.

f. Dispensing and delivery of drugs and devices from the remote site.

g. Supervision of remote site personnel.

h. Procurement, receipt, and delivery of drugs and devices to the remote site and into AMDS components.

i. Records.

j. Monthly pharmacist inspection of the remote dispensing site, including documentation of inspection.

k. The frequency of review of the policy and procedure manual and required documentation of that periodic review.

657—9.12(147,155A) System, site, and process requirements. An AMDS may be utilized on site by licensed pharmacies or in board-approved remote dispensing sites engaged in the practice of telepharmacy. Each AMDS shall comply with the following minimum requirements:

9.12(1) *System access.*

a. The AMDS shall automatically and electronically record drug access.

b. Drug access and information access records shall include, at a minimum, the date the AMDS was accessed, the identity of the individual who accessed the system, the type of transaction completed, and the identity of the accessed component.

c. Information access for the purpose of retrieving or reviewing any patient or drug record or data, when the access does not permit change or addition to the record or data, shall be exempt from the access record requirements of paragraph *"b"* of this subrule.

d. The AMDS shall include the ability to assign, discontinue, and change an individual's access to drugs and information in the AMDS.

e. A licensed pharmacist or appropriately trained pharmacy technician under the oversight of a licensed pharmacist shall fill and stock drugs into AMDS components.

f. A record of drugs filled or stocked into an AMDS component shall be maintained and shall include identification of the person filling or stocking the system and, if applicable, the person checking for accuracy.

9.12(2) *Dispensing and distributing.*

a. All containers of drugs stored in each AMDS shall be packaged and labeled in compliance with federal and state laws and regulations.

b. All aspects of handling controlled substances dispensed utilizing an AMDS shall be in compliance with the requirements of all state and federal laws and regulations.

c. Each centralized or decentralized AMDS shall provide a mechanism for securing and accounting for drugs removed from and subsequently returned to the system. Drugs removed from a system component but not administered to a patient shall be returned to the pharmacy or maintained in a manner that would prevent access to the returned drugs except for the purpose of returning the drugs to the pharmacy. The provisions of this paragraph regarding preventing access to returned drugs except for return to the pharmacy shall not apply, for a decentralized unit dose AMDS, to items that are too large or bulky to be inserted into the system's return bin, to items requiring refrigeration, or to limited critical care items whose inaccessibility would compromise patient care. The provisions of this paragraph shall not apply to an AMDS utilized in telepharmacy.

d. Each centralized or decentralized AMDS shall provide a mechanism for securing and accounting for wasted or discarded drugs in compliance with federal and state laws and regulations. The provisions of this paragraph shall not apply to an AMDS utilized in telepharmacy.

e. An AMDS utilized in telepharmacy shall not permit the wasting or discarding of drugs. The automated pharmacy system shall provide that any drugs removed from the AMDS component but not delivered to the patient shall be maintained in a manner that prevents access to the drugs except for the purpose of returning the drugs to the managing pharmacy. The technician at a remote dispensing site shall not accept drugs returned by a patient or patient's agent.

9.12(3) *Security and confidentiality.* An AMDS shall include system safeguards designed to prevent and detect unauthorized drug access, including access to controlled substances. System safeguards shall also be designed to prevent and detect unauthorized access to information for the purpose of modification or manipulation of patient records and prescription drug orders.

a. An AMDS shall be capable of generating reports of all drug access activity. Reports shall include, at a minimum for each drug access record, the following:

(1) Identification of the person accessing the drug or drug bin.
(2) The date and, preferably, the time.
(3) Identification of the specific drug or drug bin.
(4) Whether the drug access involved stocking, dispensing, wasting, or returning the drug.
(5) The quantity of the drug.
(6) The accessed component.

b. An AMDS shall maintain confidential patient records and information in compliance with rules 657—8.16(124,155A) and 657—21.2(124,155A).

657—9.13(147,155A) Records. All records required pursuant to these rules, unless otherwise specifically identifying a different retention period, shall be available to the board or its authorized agents for two years following the recorded activity.

657—9.14 Reserved.

657—9.15(147,155A) Decentralized unit dose AMDS. Components of a decentralized unit dose AMDS utilized for the storage and dispensing of drugs in an institutional setting may be restocked with drugs by an appropriately trained pharmacy technician following pharmacist verification in the pharmacy of each dose of the drug to be restocked. The provisions of either subrule 9.15(1) or 9.15(2)

shall also apply based on whether or not bar coding or other technology-based verification is utilized to check the accuracy of drug dose placement in the AMDS component.

9.15(1) *No technology-based verification is available or used.* When bar coding or other technology-based verification is not utilized to check the accuracy of drug doses stocked in a dispensing component, a pharmacist shall check each drug dose prior to releasing the drugs from the pharmacy.

a. Following restocking of drug doses into the AMDS component, a pharmacist or a nurse shall verify that 100 percent of all drug doses are accurately placed in each drug bin of each dispensing component.

b. Policies, procedures, and safeguards shall be developed and implemented that control, while ensuring availability and access to needed drugs, utilization of drugs added to the dispensing component prior to pharmacist or nurse verification of the addition. Policies and procedures shall also provide for documentation identifying the individual who provides verification of drugs stocked in dispensing components.

9.15(2) *Bar coding or technology-based verification is available and used.* When bar coding or other technology-based verification is utilized to check the accuracy of drug doses stocked in a dispensing component and a nonpharmacist fills the component, a pharmacist shall check each drug dose prior to releasing the drugs from the pharmacy. The quality assurance plan shall provide for random verification by a pharmacist utilizing one of the methods described in paragraphs *"a"* and *"b"* below. A pharmacy may petition the board pursuant to 657—Chapter 34 for a variance for an alternate pharmacist verification process.

a. One day each month, all drug doses or bins contained in 5 percent of the components utilized within the system shall be verified by a pharmacist.

b. One day each month, 5 percent of the drug doses or bins contained in each component utilized within the system shall be verified by a pharmacist. If, however, the system includes fewer than five components, a pharmacist shall, one day each month, verify all drug doses or bins contained in one component utilized within the system.

9.15(3) *Errors identified.* All identified errors shall be logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.10(147,155A) and shall be categorized as follows:

a. Incorrect drug;

b. Incorrect dose;

c. Incorrect dosage form;

d. Other errors. All errors categorized as "other errors" shall include additional notation identifying the error.

657—9.16(147,155A) Centralized unit dose AMDS. The quality assurance plan shall provide for pharmacist verification of all drug doses dispensed for a minimum of 60 days following implementation of the AMDS.

9.16(1) *Errors logged.* All identified errors shall be logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.10(147,155A) and shall be categorized as follows:

a. Computer order entry error;

b. Incorrect drug;

c. Incorrect dose;

d. Incorrect quantity — extra dose(s);

e. Incorrect quantity — short dose(s);

f. Incorrect dosage form;

g. Other errors. All errors categorized as "other errors" shall include additional notation identifying the error.

9.16(2) *Initial report to the board.* The first quarterly report to the board shall summarize identified errors by category and shall include the total number of errors identified, the reasons for the errors, the corrective actions taken to prevent the recurrence of those errors, and the average accuracy (correct doses over total doses) determined for all AMDS-dispensed drugs during the first quarter following implementation.

9.16(3) *Random verification.* If the average accuracy of the AMDS during the initial 60-day period is at least 99.7 percent for all drug doses dispensed, the quality assurance plan shall provide for random verification by a pharmacist. The plan shall provide that 5 percent of all drug doses dispensed daily utilizing the AMDS be verified by a pharmacist, or it shall provide that 100 percent of all drug doses dispensed on a specific day each month be verified by a pharmacist. A pharmacy may petition the board pursuant to 657—Chapter 34 for a variance for an alternate pharmacist verification process. Errors shall continue to be identified and logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.10(147,155A) and shall be categorized as provided in subrule 9.16(1).

If the average accuracy of the AMDS during the initial 60-day period is not at least 99.7 percent for all drug doses dispensed, the pharmacy shall continue pharmacist verification of all drug doses dispensed utilizing the AMDS until the average accuracy for 60 consecutive days is at least 99.7 percent.

9.16(4) *Reports during first year.* For a minimum of one year following implementation of the AMDS, written quarterly reports shall be submitted to the board. Reports shall summarize identified errors by category and shall include the total number of errors identified, the reasons for the errors, the corrective actions taken to prevent the recurrence of those errors, and the average accuracy (correct doses over total verified doses) for all drug doses verified during the preceding quarter.

9.16(5) *Accuracy.* Any random verification disclosing accuracy of less than 99.7 percent for all drug doses verified shall require that a pharmacist again verify all drug doses dispensed utilizing the AMDS until the average accuracy equals or exceeds 99.7 percent for all drug doses dispensed for three consecutive days.

9.16(6) *Continued verification.* The quality assurance plan shall provide for continuation, as long as the pharmacy utilizes the AMDS, of random verification by the pharmacist of AMDS-dispensed drug doses as provided in subrules 9.16(3) and 9.16(5).

9.16(7) *Reports after one year.* Following the one-year period and within 30 days of determining by random verification that the accuracy of AMDS drug fills is less than 99.7 percent for all drug doses verified, a written report shall be submitted to the board. The report shall summarize the identified errors by category and shall include the reasons for the errors, the corrective actions taken to prevent the recurrence of those errors, and the low accuracy rate prompting the report.

657—9.17(147,155A) Outpatient AMDS.

9.17(1) *Verification.* All outpatient prescriptions prepared for dispensing utilizing an AMDS shall be verified, prior to being dispensed, by a pharmacist in the pharmacist's physical presence unless a waiver is approved pursuant to subrule 9.17(2) or as provided in these rules for telepharmacy.

9.17(2) *Waiver.* A pharmacy may request waiver or variance from subrule 9.17(1) pursuant to the procedures and requirements of 657—Chapter 34. In addition to the requirements for the petition for waiver or variance identified in 657—Chapter 34, applications for waiver shall specify and include justification for the requested waiver, the methods to be used to ensure patient counseling is provided on new prescriptions pursuant to 657—8.20(155A), a quality assurance plan, and written policies and procedures for utilization of the AMDS.

a. Quarterly reports. The quality assurance plan shall provide for submission of written quarterly reports to the board. All reports shall summarize identified errors by category and shall include the reasons for the errors, the corrective actions taken to resolve and prevent recurrence of the errors, and the average accuracy for the specified period.

b. Verification. The quality assurance plan shall provide for verification processes for all AMDS-dispensed prescriptions.

c. Identification of errors. The quality assurance plan shall require that all identified errors be logged as provided by the quality assurance and monitoring plan developed pursuant to rule 9.10(147,155A) and shall be categorized as follows:

(1) Incorrect drug;
(2) Incorrect quantity;
(3) Incorrect dose;
(4) Incorrect dosage form;

(5) Incorrect directions for use;
(6) Incorrect patient name;
(7) Other incorrect label information;
(8) Computer order entry error;
(9) Other errors. All errors categorized as "other errors" shall include additional notation identifying each error.

d. Accuracy. The performance improvement plan shall identify actions to be taken in the event that any drug error is identified.

657—9.18(124,155A) Remote dispensing site operations.

9.18(1) *Automated pharmacy system.* On any day when the remote site is opened and prior to providing telepharmacy services, the managing pharmacy shall perform a test of the automated pharmacy system with the remote site to ensure proper operation. A log shall be created and maintained that includes the date and the test results and that identifies the individual performing the test.

9.18(2) *Remote site staffing.* A remote dispensing site shall be staffed by one or more qualified certified pharmacy technicians under the continuous supervision of a pharmacist at the managing pharmacy at all times that the remote site is open to provide telepharmacy services. Continuous supervision does not require the pharmacist to be physically present at the remote dispensing site, but the pharmacist shall supervise telepharmacy operations electronically through the automated pharmacy system.

9.18(3) *Supervising pharmacists.* The managing pharmacy shall have a sufficient number of pharmacists on duty to ensure that a pharmacist is able to provide all services offered by the managing pharmacy and to ensure appropriate supervision of all telepharmacy services. The board may limit the number of remote dispensing sites under the management of a single managing pharmacy.

9.18(4) *Prescription drug orders.* A remote dispensing site may receive written or electronic prescription drug orders or refill requests in accordance with the policies and procedures designated by the pharmacist in charge. As provided in policies and procedures, the qualified certified pharmacy technician at the remote site shall either transmit the prescription drug order or refill request to the managing pharmacy or input the prescription drug order or refill request so that the pharmacist at the managing pharmacy may perform a prospective drug use review and verify the prescription information prior to authorizing dispensing at the remote site. A pharmacy technician at a remote site shall not receive oral prescription drug orders from a prescriber or prescriber's agent. Oral prescription drug orders shall be communicated directly to a pharmacist.

9.18(5) *Drug use review.* A pharmacist at the managing pharmacy shall conduct a drug use review as specified in 657—8.21(155A) prior to authorizing delivery of the prescription to the patient or the patient's caregiver at the remote dispensing site.

9.18(6) *Prescription label.* A prescription dispensed at a remote site shall be labeled with the following information:

a. Serial number (a unique identification number of the prescription) which shall, in some manner, identify the remote site that dispensed the prescription.
b. The name and address of the remote dispensing site.
c. The name, address, and telephone number of the managing pharmacy.
d. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of the owner.
e. The name of the prescribing practitioner.
f. The date on which the prescription is dispensed.
g. The directions or instructions for use, including precautions to be observed.
h. The initials or other unique identification of the supervising pharmacist at the managing pharmacy and of the technician who dispenses the prescription at the remote dispensing site.
i. The name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)."

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)."

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 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.

9.18(8) *Patient counseling.* A remote dispensing site shall contain an appropriate area for patient counseling. The area shall be readily accessible to patients and be designed to maintain the confidentiality and privacy of a patient's conversation with the pharmacist. A pharmacist at the managing pharmacy shall utilize the video and audio components of the automated pharmacy system to counsel each patient or the patient's caregiver on all new prescriptions pursuant to 657—6.14(155A). As provided in subrule 9.5(4), a sign shall be posted at the remote site to ensure that all patients are informed that a pharmacist will provide counseling regarding any prescription dispensed from the remote site. A nonpharmacist may not extend an offer to counsel or ask questions of a patient or the patient's caregiver if such offer is intended to screen or limit the patient's interaction with a pharmacist.

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09]

657—9.19 Reserved.

657—9.20(124,155A) Drugs at a remote dispensing site. Policies and procedures of the managing pharmacy shall establish criteria for the delivery and storage of drugs at the remote dispensing site including but not limited to the provisions of this rule. If controlled substances are maintained or dispensed from the remote dispensing site, the transfer of those controlled substances from the managing pharmacy to the remote site shall comply with federal and state requirements for the sale or transfer of controlled substances between registrants, including the use of DEA Form 222 for the transfer of Schedule II controlled substances.

9.20(1) *Drug delivery and verification.* Drugs shall only be delivered to the remote dispensing site in a sealed container with a list identifying the drugs, including drug strength and quantities, included in the container. Drugs shall not be delivered to the remote site unless a remote site staff member designated by the pharmacist in charge to receive and check the drugs is present at the remote site to accept delivery and verify that the drugs sent were actually received. The designated individual who receives and checks the order shall document the verification by signing and dating the list of drugs delivered.

9.20(2) *Limited drug inventory.* A remote dispensing site may maintain a limited drug inventory for the purpose of restocking the AMDS. The pharmacist at the managing pharmacy shall ensure, through

use of the electronic audio and video communications system or bar code technology, that the qualified certified pharmacy technician has accurately and correctly restocked drugs into AMDS components.

9.20(3) *Drug storage.* Drugs at a remote dispensing site shall be stored in a manner to protect their identity and integrity including the requirements of 657—Chapter 8 relating to environment, temperature, and handling of outdates. Drugs shall be stored in a secure area, and access to any drugs maintained at a remote site shall be limited to pharmacists from the managing pharmacy and qualified certified pharmacy technicians who have been so authorized, in writing, by the pharmacist in charge.

657—9.21(124,155A) Record keeping. In addition to records identified elsewhere in state and federal laws and regulations, the following records of a managing pharmacy and a remote dispensing site shall be maintained as provided herein.

9.21(1) *Electronic records.* All electronic records shall be available to, and accessible from, both the managing pharmacy and the remote dispensing site.

9.21(2) *Receipt, dispensing, and distribution records.* Except as provided in this subrule, a managing pharmacy shall maintain a record of all drugs received, dispensed, and distributed from the managing pharmacy and from each remote dispensing site.

a. Records of the receipt, dispensing, and distribution of controlled substances from a remote dispensing site, including controlled substances inventory records for the remote site, that are required by the DEA to be maintained at the registered location shall be maintained at the remote site.

b. Records of the managing pharmacy and of each remote dispensing site shall be maintained separately from each other.

These rules are intended to implement Iowa Code sections 147.107, 155A.13, and 155A.33.

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CHAPTER 10
CONTROLLED SUBSTANCES

[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 8]

657—10.1(124) Who shall register. 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 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.

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.

657—10.2(124) Application forms. Application forms may be obtained from the Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Forms are also available on the board's Web site, www.state.ia.us/ibpe. Registration renewal forms will be mailed to each registrant approximately 60 days before the expiration date of the registration. A registrant who has not received a renewal form 45 days before the expiration date of the registration is responsible for contacting the board to request an application.

10.2(1) *Signature requirements.* Each application, attachment, or other document filed as part of an application shall be signed by the applicant as follows:

a. If the applicant is an individual practitioner, the practitioner shall sign the application and supporting documents.

b. If the applicant is a business, the application and supporting documents shall be signed by the person ultimately responsible for the security and maintenance of controlled substances at the registered location.

10.2(2) *Submission of multiple applications.* Any person or business required to obtain more than one registration may submit all applications in one package. Each application shall be complete and shall not refer to any accompanying application or any attachment to an accompanying application for required information.

657—10.3(124) Registration and renewal. For each registration or timely renewal of a registration to manufacture, distribute, dispense, prescribe, import or export, conduct research or instructional activities, or conduct chemical analysis with controlled substances listed in Schedules I through V of Iowa Code chapter 124, registrants shall pay a biennial fee of $100.

10.3(1) *Time and method of payment.* Registration and renewal fees shall be paid at the time the application for registration or renewal is submitted. Payment should be made in the form of a personal, certified, or cashier's check or a money order made payable to the Iowa Board of Pharmacy. Payments made in the form of foreign currency or third-party endorsed checks will not be accepted.

10.3(2) *Late renewal.* Any registered person or business may apply, on forms provided by the board office, for registration renewal not more than 60 days prior to the expiration of the registration. Failure to renew a registration prior to the first day of the month following expiration shall require payment of the renewal fee and a penalty fee of $100. Payment shall be made as specified in subrule 10.3(1).

657—10.4(124) Exemptions—registration fee. The registration fee is waived for federal, state, and local law enforcement agencies and for the following federal and state institutions: hospitals, health care or teaching institutions, and analytical laboratories authorized to possess, manufacture, distribute, and dispense controlled substances in the course of official duties.

10.4(1) *Law enforcement officials.* In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories shall maintain a registration to conduct chemical analysis. Such laboratories shall be exempt from payment of a fee for registration.

10.4(2) *Registration and duties not exempt.* Exemption from payment of a registration or registration renewal fee as provided in this rule does not relieve the agency or institution of registration or of any other requirements or duties prescribed by law.

657—10.5(124) Separate registration for independent activities; coincident activities. The following activities are deemed to be independent of each other and shall require separate registration. Any person or business engaged in more than one of these activities shall be required to separately register for each independent activity, provided, however, that registration in an independent activity shall authorize the registrant to engage in activities identified coincident with that independent activity.

10.5(1) *Manufacturing controlled substances.* A person or business registered to manufacture controlled substances in Schedules I through V may distribute any substances for which registration to manufacture was issued. A person or business registered to manufacture controlled substances in Schedules II through V may conduct chemical analysis and preclinical research, including quality control analysis, with any substances listed in those schedules for which the person or business is registered to manufacture.

10.5(2) *Distributing controlled substances.* This independent activity includes the delivery, other than by administering or dispensing, of controlled substances listed in Schedules I through V. No coincident activities are authorized.

10.5(3) *Dispensing or instructing with controlled substances.* This independent activity includes, but is not limited to, prescribing by individual practitioners, dispensing by pharmacies and hospitals, and conducting instructional activities with controlled substances listed in Schedules II through V. A person or business registered for this independent activity may conduct research and instructional activities with those substances for which the person or business is registered to the extent authorized under state law.

10.5(4) *Conducting research with controlled substances listed in Schedule I.* A researcher may manufacture or import the substances for which registration was issued provided that such manufacture or import is permitted under the federal Drug Enforcement Administration (DEA) registration. A researcher may distribute the substances for which registration was issued to persons or businesses registered or authorized to conduct research with that class of substances or registered or authorized to conduct chemical analysis with controlled substances.

10.5(5) *Conducting research with controlled substances listed in Schedules II through V.* A researcher may conduct chemical analysis with controlled substances in those schedules for which registration was issued, may manufacture such substances if and to the extent such manufacture is permitted under the federal DEA registration, and may import such substances for research purposes. A researcher may distribute controlled substances in those schedules for which registration was issued to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances, and to persons exempt from registration pursuant to Iowa Code subsection 124.302(3), and may conduct instructional activities with controlled substances.

10.5(6) *Conducting chemical analysis with controlled substances.* A person or business registered to conduct chemical analysis with controlled substances listed in Schedules I through V may manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempt from registration pursuant to Iowa Code subsection 124.302(3); may export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.

10.5(7) *Importing or exporting controlled substances.* A person or business registered to import controlled substances listed in Schedules I through V may distribute any substances for which such registration was issued.

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 unless the person or business is exempt from registration pursuant to Iowa Code subsection 124.302(3) or this rule.

10.6(1) *Warehouse.* A warehouse where controlled substances are stored by or on behalf of a registered person or business shall be exempt from registration except as follows:

a. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to registered locations other than the registered location from which the substances were delivered to the warehouse.

b. Registration of the warehouse shall be required if such controlled substances are distributed directly from that warehouse to persons exempt from registration pursuant to Iowa Code subsection 124.302(3).

10.6(2) *Sales office.* An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised shall be exempt from registration. Such office shall not contain controlled substances, except substances used for display purposes or for lawful distribution as samples, and shall not serve as a distribution point for filling sales orders.

10.6(3) *Prescriber's office.* An office used by a prescriber who is registered at another location and where controlled substances are prescribed but where no supplies of controlled substances are maintained shall be exempt from registration. However, a prescriber who practices at more than one office location where controlled substances are administered or otherwise dispensed as a regular part of the prescriber's practice shall register at each location wherein the prescriber maintains supplies of controlled substances.

10.6(4) *Prescriber in hospital.* A prescriber who is registered at another location and who treats patients and may order the administration of controlled substances in a hospital other than the prescriber's registered practice location shall not be required to obtain a separate registration for the hospital.

10.6(5) *Affiliated interns, residents, or foreign physicians.* An individual practitioner who is an intern, resident, or foreign physician may dispense and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom the registrant is employed provided that:

a. The hospital or other institution by which the individual practitioner is employed has determined that the practitioner is permitted to dispense or prescribe drugs by the appropriate licensing board;

b. Such individual practitioner is acting only in the scope of employment in the hospital or institution;

c. The hospital or other institution authorizes the intern, resident, or foreign physician to dispense or prescribe under the hospital registration and designates a specific internal code number, letters, or combination thereof which shall be appended to the institution's DEA registration number, preceded by a hyphen (e.g., AP1234567-10 or AP1234567-12); and

d. The hospital or institution maintains a current list of internal code numbers identifying the corresponding individual practitioner, available for the purpose of verifying the authority of the prescribing individual practitioner.

657—10.7 to **10.9** Reserved.

657—10.10(124,147,155A) Inspection. The board may inspect, or cause to be inspected, the establishment of an applicant or registrant. The board shall review the application for registration and other information regarding an applicant or registrant in order to determine whether the applicant or registrant has met the applicable standards of Iowa Code chapter 124 and these rules.

657—10.11(124) Modification or termination of registration. A registered individual or business may apply to modify a current registration as provided by this rule.

10.11(1) *Change of substances authorized.* Any registrant may apply to modify the substances authorized by the registration by submitting a written request to the board. The request shall include the registrant's name, address, telephone number, registration number, and the substances or schedules to be

added to or removed from the registration and shall be signed by the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.

10.11(2) *Change of address of registered location.*

a. Individual practitioner, researcher, analytical laboratory, or teaching institution. An entity registered under these classifications may apply to change the address of the registered location by submitting a written request to the board. The request shall include the registrant's name, current address, new address, telephone number, effective date of the address change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification.

b. Pharmacy, hospital, care facility, manufacturer, distributor, importer, or exporter. An entity registered under these classifications shall apply to change the address of the registered location by submitting a completed application for registration. Applications may be obtained and shall be submitted as provided in rule 657—10.2(124). The registration fee as provided in rule 10.3(124) shall accompany each completed application.

10.11(3) *Change of registrant's name.*

a. Individual practitioner, researcher, analytical laboratory, or teaching institution. An entity registered under these classifications may apply to change the registrant's name by submitting a written request to the board. The request shall include the registrant's current name, the new name, address, telephone number, effective date of the name change, and registration number, and shall be signed by the registered individual practitioner or the same person who signed the most recent application for registration or registration renewal. No fee shall be required for the modification. Change of name, as used in this paragraph, refers to a change of the legal name of the registrant and does not authorize the transfer of a registration issued to an individual practitioner or researcher to another individual practitioner or researcher.

b. Pharmacy, hospital, care facility, manufacturer, distributor, importer, or exporter. An entity registered under these classifications shall apply to change the registrant name by submitting a completed application for registration. Applications may be obtained and shall be submitted as provided in rule 657—10.2(124). The registration fee as provided in rule 10.3(124) shall accompany each completed application.

10.11(4) *Change of ownership of registered business entity.* A change of immediate ownership of a pharmacy, hospital, care facility, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall require the completion of an application for registration. Applications may be obtained and shall be submitted as provided in rule 657—10.2(124). The registration fee as provided in rule 10.3(124) shall accompany each completed application.

10.11(5) *Change of responsible individual.* Any registrant, except an individual practitioner, a researcher, a hospital, or a pharmacy, may apply to change the responsible individual authorized by the registration by submitting a written request to the board. The request shall include the registrant's name, address, telephone number, the name and title of the current responsible individual and of the new responsible individual, the effective date of the change, and the registration number, and shall be signed by the new responsible individual. No fee shall be required for the modification.

a. Individual practitioners and researchers. Responsibility under a registration issued to an individual practitioner or researcher shall remain with the named individual practitioner or researcher. The responsible individual under such registration may not be changed.

b. Pharmacies and hospitals. The responsible pharmacist may execute a power of attorney for DEA order forms to change responsibility under the registration issued to the pharmacy or hospital. The power of attorney shall include the name, address, DEA registration number, and Iowa uniform controlled substances Act (CSA) registration number of the registrant. The power of attorney shall identify the current and new responsible individuals and shall authorize the new responsible individual to execute applications and official DEA order forms to requisition Schedule II controlled substances. The power of attorney shall be signed by both individuals, shall be witnessed by two adults, and shall be maintained by the registrant and available for inspection or copying by representatives of the board or other state or federal authorities.

10.11(6) *Termination of registration.* A registration issued to an individual shall terminate upon the death of the individual. A registration issued to an individual or business shall terminate when the registered individual or business ceases legal existence, discontinues business, or discontinues professional practice.

657—10.12(124) Denial, modification, suspension, or revocation of registration.

10.12(1) *Grounds for suspension or revocation.* The board may suspend or revoke any registration upon a finding that the registrant:

a. Has furnished false or fraudulent material information in any application filed under this chapter;

b. Has had the registrant's federal registration to manufacture, distribute, or dispense controlled substances suspended or revoked;

c. Has been convicted of a public offense under any state or federal law relating to any controlled substance. For the purpose of this rule only, a conviction shall include a plea of guilty, a forfeiture of bail or collateral deposited to secure a defendant's appearance in court which forfeiture has not been vacated, or a finding of guilt in a criminal action even though entry of the judgment or sentence has been withheld and the individual has been placed on probation;

d. Has committed such acts as would render the registrant's registration under Iowa Code section 124.303 inconsistent with the public interest as determined by that section; or

e. Has been subject to discipline by the registrant's respective professional licensing board and the discipline revokes, suspends, or modifies the registrant's authority regarding controlled substances (including, but not limited to, limiting or prohibiting the registrant from prescribing or handling controlled substances). A certified copy of the record of licensee discipline or a copy of the licensee's surrender of the professional license shall be conclusive evidence.

10.12(2) *Limited suspension or revocation.* If the board finds grounds to suspend or revoke a registration, the board may limit revocation or suspension of the registration to the particular controlled substance with respect to which the grounds for revocation or suspension exist. If the revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new certificate of registration for all substances not affected by revocation or suspension; no fee shall be required for the new certificate of registration. The registrant shall deliver the old certificate of registration to the board.

10.12(3) *Denial of registration or registration renewal.* If upon examination of an application for registration or registration renewal, including any other information the board has or receives regarding the applicant, the board determines that the issuance of the registration would be inconsistent with the public interest, the board shall serve upon the applicant an order to show cause why the registration should not be denied.

10.12(4) *Considerations in denial of registration.* In determining the public interest, the board shall consider all of the following factors:

a. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.

b. Compliance with applicable state and local law.

c. Any convictions of the applicant under any federal and state laws relating to any controlled substance.

d. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion.

e. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter.

f. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law.

g. Any other factors relevant to and consistent with the public health and safety.

10.12(5) *Order to show cause.* Before denying, modifying, suspending, or revoking a registration, the board shall serve upon the applicant or registrant an order to show cause why the registration should

not be denied, modified, revoked, or suspended. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before an administrative law judge or the board at a time and place not less than 30 days after the date of service of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted. If the order to show cause involves the possible denial of registration renewal, the order shall be served not later than 30 days before the expiration of the registration. Proceedings to refuse renewal of registration shall not abate the existing registration, which shall remain in effect pending the outcome of the administrative hearing unless the board issues an order of immediate suspension pursuant to subrule 10.12(9).

10.12(6) *Hearing requested.* If an applicant or registrant who has received an order to show cause desires a hearing on the matter, the applicant or registrant shall file a request for a hearing within 30 days after the date of service of the order to show cause. If a hearing is requested, the board shall hold a hearing pursuant to 657—Chapter 35 at the time and place stated in the order and without regard to any criminal prosecution or other proceeding. Unless otherwise ordered by the board, an administrative law judge employed by the department of inspections and appeals shall be assigned to preside over the case and to render a proposed decision for the board's consideration.

10.12(7) *Waiver of hearing.* If an applicant or registrant entitled to a hearing on an order to show cause fails to file a request for hearing, or if the applicant or registrant requests a hearing but fails to appear at the hearing, the applicant or registrant shall be deemed to have waived the opportunity for a hearing unless the applicant or registrant shows good cause for such failure.

10.12(8) *Final board order when hearing waived.* If an applicant or registrant entitled to a hearing waives or is deemed to have waived the opportunity for a hearing, the executive director of the board may cancel the hearing and issue, on behalf of the board, the board's final order on the order to show cause.

10.12(9) *Order of immediate suspension.* The board may suspend any registration simultaneously with the service upon the registrant of an order to show cause why such registration should not be revoked or suspended if it finds there is an imminent danger to the public health or safety that warrants such action. If the board suspends a registration simultaneously with the service of the order to show cause upon the registrant, it shall serve an order of immediate suspension containing a statement of its findings regarding the danger to public health or safety upon the registrant with the order to show cause. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, under the provisions of the Iowa administrative procedure Act, unless sooner withdrawn by the board or dissolved by the order of the district court or an appellate court.

10.12(10) *Disposition of controlled substances.* If the board suspends or revokes a registration, the registrant shall promptly return the certificate of registration to the board. Also, upon service of the order of the board suspending or revoking the registration, the registrant shall deliver all affected controlled substances in the registrant's possession to the board or authorized agent of the board. Upon receiving the affected controlled substances from the registrant, the board or its authorized agent shall place all such substances under seal and retain the sealed controlled substances pending final resolution of any appeals or until a court of competent jurisdiction directs otherwise. No disposition may be made of the substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application, orders the sale of perishable substances and the deposit of proceeds of the sale with the court. Upon a revocation order's becoming final, all such controlled substances may be forfeited to the state.

10.12(11) *Notifications.* The board shall promptly notify the DEA and the Iowa department of public safety of all orders suspending or revoking registration and all forfeitures of controlled substances.

657—10.13 and **10.14** Reserved.

657—10.15(124,155A) Security requirements. All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a person has provided effective controls against diversion, the board shall use

the security requirements set forth in these rules as standards for the physical security controls and operating procedures necessary to prevent diversion.

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. Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

b. Controlled substances listed in Schedules II through V may be stored in a securely locked, substantially constructed cabinet. However, pharmacies and hospitals may disperse these substances throughout the stock of noncontrolled substances in a manner so as to obstruct the theft or diversion of the controlled substances.

10.15(2) *Factors in evaluating physical security systems.* In evaluating the overall security system of a registrant or applicant necessary to maintain effective controls against theft or diversion of controlled substances, the board may consider any of the following factors it deems relevant to the need for strict compliance with the requirements of this rule:

a. The type of activity conducted;

b. The type, form, and quantity of controlled substances handled;

c. The location of the premises and the relationship such location bears to security needs;

d. The type of building construction comprising the facility and the general characteristics of the building or buildings;

e. The type of vault, safe, and secure enclosures available;

f. The type of closures on vaults, safes, and secure enclosures;

g. The adequacy of key control systems or combination lock control systems;

h. The adequacy of electric detection and alarm systems, if any;

i. The adequacy of supervision over employees having access to controlled substances, to storage areas, or to manufacturing areas;

j. The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

k. The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;

l. The availability of local police protection or of the registrant's or applicant's security personnel; and

m. The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances.

10.15(3) *Manufacturing and compounding storage areas.* Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in any schedule shall be stored pursuant to federal laws and regulations.

657—10.16(124) Report of theft or loss. A registrant shall report in writing, on forms provided by the board, any theft or significant loss of any controlled substance when the loss is attributable to other than inadvertent error. The report shall be submitted to the board office within two weeks of the discovery of the theft or loss. Thefts shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action is taken against them. A copy of the report shall be maintained in the files of the registrant, and the board will provide a copy of the report to the DEA. In addition to this required report, DEA requires the registrant to deliver notice, immediately upon discovery of a theft or significant loss of controlled substances, to the nearest DEA field office via telephone, facsimile, or a brief written message explaining the circumstances.

657—10.17(124) Accountability of stock supply. An individual who administers a controlled substance from a non-patient-specific, stock supply in an institutional setting shall personally document on a separate readily retrievable record system each dose administered, wasted, or returned to the

pharmacy. Such documentation shall not be delegated to another individual. Wastage documentation shall include the signature of a witnessing licensed health care practitioner.

Distribution records for non-patient-specific, floor-stocked controlled substances shall bear the following information:

1. Patient's name;
2. Prescriber who ordered drug;
3. Name of drug, dosage form, and strength;
4. Time and date of administration to patient and quantity administered;
5. Signature or unique electronic signature of individual administering controlled substance;
6. Returns to the pharmacy;
7. Waste, which is required to be witnessed and cosigned by another licensed health care practitioner.

657—10.18(124) Disposal. 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 the registrant.

10.18(1) *Registrant stock supply.* Pharmacy personnel, registrants, and registrant staff shall remove from current inventory and dispose of controlled substances by one of the following procedures.

a. The responsible individual shall utilize the services of a DEA-registered and Iowa-licensed disposal firm.

b. The board may authorize and instruct the registrant to dispose of the controlled substances in one of the following manners:

(1) By delivery to an agent of the board or to the board office;

(2) By destruction of the drugs in the presence of a board officer, agent, inspector, or other authorized individual; or

(3) By such other means as the board may determine to ensure that drugs do not become available to unauthorized persons.

10.18(2) *Waste.* Except as otherwise specifically provided by federal or state law or rules of the board, the unused portion of a controlled substance resulting from administration to a patient from a registrant's stock or emergency supply or resulting from drug compounding operations may be destroyed or otherwise disposed of by the registrant or a pharmacist in witness of one other licensed health care provider or a registered pharmacy technician 18 years of age or older pursuant to this subrule. A written record of the wastage shall be made and maintained by the registrant for a minimum of two years following the destruction or other disposal. The record shall include the signatures of the individual destroying or otherwise disposing of the waste controlled substance and of the witnessing licensed health care provider or registered pharmacy technician and shall identify the following:

a. The controlled substance wasted;

b. The date of destruction or other disposition;

c. The quantity or estimated quantity of the wasted controlled substance;

d. The source of the controlled substance, including identification of the patient to whom the substance was administered or the drug compounding process utilizing the controlled substance; and

e. The reason for the waste.

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 of the controlled substance (patient identifier or administering practitioner, if applicable, and date of return);

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

c. The quantity returned and destroyed or otherwise disposed;

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

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

657—10.19 and **10.20** Reserved.

657—10.21(124,126,155A) Prescription requirements. All prescriptions for controlled substances shall be dated as of, and manually signed on, the day issued. Controlled substances prescriptions shall be valid for six months following date of issue.

10.21(1) *Form of prescription.* All prescriptions shall bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; and the name, address, and DEA registration number of the prescriber. All prescriptions issued by individual prescribers shall include the legibly preprinted, typed, or hand-printed name of the prescriber as well as the prescriber's signature. When an oral order is not permitted, prescriptions shall be written with ink, indelible pencil, or typed print and shall be manually signed by the prescriber. A secretary or agent may prepare a prescription for the signature of the prescriber but the prescribing practitioner is responsible for the accuracy, completeness, and validity of the prescription. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this rule.

10.21(2) *Verification by pharmacist.* The pharmacist shall verify the authenticity of the prescription with the individual prescriber in each case when a prescription for a Schedule II controlled substance is presented for filling and neither the prescribing individual practitioner issuing the prescription nor the patient or patient's agent is known to the pharmacist. The pharmacist is required to record the manner by which the prescription was verified and include the pharmacist's name or unique identifier.

10.21(3) *Intern, resident, foreign physician.* An intern, resident, or foreign physician exempt from registration pursuant to subrule 10.6(5) shall include on all prescriptions issued the hospital's registration number and the special internal code number assigned by the hospital in lieu of the prescriber's registration number required by this rule. Each prescription shall include the stamped or printed name of the intern, resident, or foreign physician as well as the prescriber's signature.

10.21(4) *Valid prescriber/patient relationship.* Once the prescriber/patient relationship is broken and the prescriber is no longer available to treat the patient or to oversee the patient's use of the controlled substance, a prescription shall lose its validity. A prescriber/patient relationship shall be deemed broken when the prescriber dies, retires, or moves out of the local service area or when the prescriber's authority to prescribe is suspended, revoked, or otherwise modified to exclude authority for the schedule in which the prescribed substance is listed. The pharmacist, upon becoming aware of the situation, shall cancel the prescription and any remaining refills. However, the pharmacist shall exercise prudent judgment based upon individual circumstances to ensure that the patient is able to obtain a sufficient amount of the drug to continue treatment until the patient can reasonably obtain the service of another prescriber and a new prescription can be issued.

10.21(5) *Schedule II prescriptions.* With appropriate verification, a pharmacist may add information provided by the patient or patient's agent, such as the patient's address, to a Schedule II controlled substance prescription. A pharmacist shall never change the patient's name, the controlled substance prescribed except for generic substitution, or the name or signature of the prescriber. After consultation with the prescribing practitioner and documentation of such consultation, a pharmacist may change or add the following information on a Schedule II controlled substance prescription:

a. The drug strength;

b. The dosage form;
c. The drug quantity;
d. The directions for use; and
e. The date the prescription was issued.

657—10.22(124) Schedule II emergency prescriptions.

10.22(1) *Emergency situation defined.* For the purposes of authorizing an oral or electronically transmitted prescription for a Schedule II controlled substance listed in Iowa Code section 124.206, the term "emergency situation" means those situations in which the prescribing practitioner determines that all of the following apply:

a. Immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.

b. No appropriate alternative treatment is available, including administration of a drug that is not a Schedule II controlled substance.

c. It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance prior to the dispensing.

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.

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."*

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.

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09]

657—10.23(124) Schedule II prescriptions—partial filling. The partial filling of a prescription for a controlled substance listed in Schedule II is permitted as provided in this rule.

10.23(1) *Insufficient supply on hand.* If the pharmacist is unable to supply the full quantity called for in a prescription and makes a notation of the quantity supplied on the prescription record, a partial fill of the prescription is permitted. The remaining portion of the prescription must be filled within 72 hours of the first partial filling. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescriber. No further quantity may be supplied beyond 72 hours without a new prescription.

10.23(2) *Long-term care or terminally ill patient.* A prescription for a Schedule II controlled substance written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units as provided by this subrule.

a. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient.

b. The pharmacist shall record on the prescription whether the patient is "terminally ill" or an "LTCF patient." For each partial filling, the dispensing pharmacist shall record on the back of the prescription, or on another appropriate uniformly maintained and readily retrievable record, the date of the partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

c. The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug.

d. Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system pursuant to rule 657—21.4(124,155A).

657—10.24(124) Schedule II medication order. Schedule II controlled substances may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.18(124,155A), as applicable.

657—10.25(124) Schedule II—issuing multiple prescriptions. An individual prescriber may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance pursuant to the provisions and limitations of this rule.

10.25(1) *Refills prohibited.* The issuance of refills for a Schedule II controlled substance is prohibited. The use of multiple prescriptions for the dispensing of Schedule II controlled substances, pursuant to this rule, ensures that the prescriptions are treated as separate dispensing authorizations and not as refills of an original prescription.

10.25(2) *Legitimate medical purpose.* Each separate prescription issued pursuant to this rule shall be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber's professional practice.

10.25(3) *Dates and instructions.* Each prescription issued pursuant to this rule shall be dated as of and manually signed by the prescriber on the day the prescription is issued. Each separate prescription, other than the first prescription if that prescription is intended to be filled immediately, shall contain written instructions indicating the earliest date on which a pharmacist may fill each prescription.

10.25(4) *Authorized fill date unalterable.* Regardless of the provisions of subrule 10.21(5), when a prescription contains instructions from the prescriber indicating that the prescription shall not be filled before a certain date, a pharmacist shall not fill the prescription before that date. The pharmacist shall not contact the prescriber for verbal authorization to fill the prescription before the fill date originally indicated by the prescriber pursuant to this rule.

10.25(5) *Number of prescriptions and authorized quantity.* An individual prescriber may issue for a patient as many separate prescriptions, to be filled sequentially pursuant to this rule, as the prescriber

deems necessary to provide the patient with adequate medical care. The cumulative effect of the filling of each of these separate prescriptions shall result in the receipt by the patient of a quantity of the Schedule II controlled substance not exceeding a 90-day supply.

10.25(6) *Prescriber's discretion.* Nothing in this rule shall be construed as requiring or encouraging an individual prescriber to issue multiple prescriptions pursuant to this rule or to see the prescriber's patients only once every 90 days when prescribing Schedule II controlled substances. An individual prescriber shall determine, based on sound medical judgment and in accordance with established medical standards, how often to see patients and whether it is appropriate to issue multiple prescriptions pursuant to this rule.

[**ARC 8172B**, IAB 9/23/09, effective 10/28/09]

657—10.26 Reserved.

657—10.27(124,155A) Facsimile transmission of a controlled substance prescription.

10.27(1) *Schedule II prescription.* A prescription for a Schedule II controlled substance may be transmitted via facsimile to the pharmacy only as provided in rules 657—21.12(124,155A) to 657—21.16(124,155A).

10.27(2) *Schedule III, IV, or V prescription.* A prescription for a Schedule III, IV, or V controlled substance may be transmitted via facsimile to the pharmacy only as provided in rule 657—21.9(124,155A).

657—10.28(124,155A) Schedule III, IV, or V refills. No prescription for a controlled substance listed in Schedule III, IV, or V shall be filled or refilled more than six months after the date on which it was issued nor be refilled more than five times.

10.28(1) *Record.* Each filling and refilling of a prescription shall be entered on the prescription or on another uniformly maintained and readily retrievable record.

a. The following information shall be retrievable by the prescription number: the name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, the unique identification of the dispensing pharmacist for each refill, and the total number of refills authorized for that prescription.

b. If the pharmacist merely initials or affixes the pharmacist's unique identifier and dates the back of the prescription, it shall be deemed that the full face amount of the prescription has been dispensed.

10.28(2) *Oral refill authorization.* The prescribing practitioner may authorize additional refills of Schedule III, IV, or V controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

a. The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issuance of the original prescription.

b. The pharmacist who obtains the oral authorization records from the prescriber who issued the original prescription records on or with the original prescription the date, the quantity of each refill, the number of additional refills authorized, and the pharmacist's unique identification.

c. The quantity of each additional refill is equal to or less than the quantity authorized for the initial filling of the original prescription.

d. The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

10.28(3) *Automated data processing record system.* An automated data processing record system may be used for the storage and retrieval of Schedule III, IV, and V controlled substance prescription fill and refill information subject to the conditions and requirements of rules 657—21.4(124,155A) and 657—21.5(124,155A).

657—10.29(124,155A) Schedule III, IV, or V partial fills. The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that each partial fill is recorded in the same manner as a refill. The total quantity dispensed in all partial fills shall not exceed

the total quantity prescribed. No dispensing shall occur later than six months after the date on which the prescription was issued.

657—10.30(124,155A) Schedule III, IV, and V medication order. A Schedule III, IV, or V controlled substance may be administered or dispensed to institutionalized patients pursuant to a medication order as provided in 657—subrule 7.13(1) or rule 657—23.9(124,155A), as applicable.

657—10.31(124,155A) Dispensing Schedule V controlled substances without a prescription. A controlled substance listed in Schedule V, which substance is not a prescription drug as determined under the federal Food, Drug and Cosmetic Act, and excepting products containing ephedrine, pseudoephedrine, or phenylpropanolamine, may be dispensed or administered without a prescription by a pharmacist to a purchaser at retail pursuant to the conditions of this rule.

10.31(1) *Who may dispense.* Dispensing shall be by a licensed Iowa pharmacist or by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor. This subrule does not prohibit, after the pharmacist has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by a nonpharmacist.

10.31(2) *Frequency and quantity.* Dispensing at retail to the same purchaser in any 48-hour period shall be limited to no more than one of the following quantities of a Schedule V controlled substance:

a. 240 cc (8 ounces) of any controlled substance containing opium.

b. 120 cc (4 ounces) of any other controlled substance.

c. 48 dosage units of any controlled substance containing opium.

d. 24 dosage units of any other controlled substance.

10.31(3) *Age of purchaser.* The purchaser shall be at least 18 years of age.

10.31(4) *Identification.* The pharmacist shall require every purchaser under this rule not known by the pharmacist to present a government-issued photo identification, including proof of age when appropriate.

10.31(5) *Record.* A bound record book (i.e., with pages sewn or glued to the spine) for dispensing of Schedule V controlled substances pursuant to this rule shall be maintained by the pharmacist. The book shall contain the name and address of each purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or unique identification of the pharmacist or pharmacist-intern who approved the dispensing of the substance to the purchaser.

10.31(6) *Prescription not required under other laws.* No other federal or state law or regulation requires a prescription prior to distributing or dispensing a Schedule V controlled substance.

657—10.32(124,155A) Dispensing products containing ephedrine, pseudoephedrine, or phenylpropanolamine. A product containing ephedrine, pseudoephedrine, or phenylpropanolamine, which substance is a Schedule V controlled substance and is not listed in another controlled substance schedule, may be dispensed or administered without a prescription by a pharmacist to a purchaser at retail pursuant to the conditions of this rule.

10.32(1) *Who may dispense.* Dispensing shall be by a licensed Iowa pharmacist or by a registered pharmacist-intern under the direct supervision of a pharmacist preceptor. This subrule does not prohibit, after the pharmacist has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by a nonpharmacist.

10.32(2) *Packaging of nonliquid forms.* A nonliquid form of a product containing ephedrine, pseudoephedrine, or phenylpropanolamine includes gel caps. Nonliquid forms of these products to be sold pursuant to this rule shall be packaged either in blister packaging with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches.

10.32(3) *Frequency and quantity.* Dispensing at retail to the same purchaser within any 30-day period shall be limited to products collectively containing no more than 7,500 mg of ephedrine,

pseudoephedrine, or phenylpropanolamine; dispensing at retail to the same purchaser within a single calendar day shall not exceed 3,600 mg.

10.32(4) *Age of purchaser.* The purchaser shall be at least 18 years of age.

10.32(5) *Identification.* The pharmacist shall require every purchaser under this rule to present a government-issued photo identification, including proof of age when appropriate. The pharmacist shall be responsible for verifying that the name on the identification matches the name provided by the purchaser and that the photo image depicts the purchaser.

10.32(6) *Record.* A legible dispensing record shall be created and maintained for the dispensing of ephedrine, pseudoephedrine, and phenylpropanolamine products pursuant to this rule.

a. Record contents. The record shall contain the following:

(1) The name, address, and signature of the purchaser.

(2) The name and quantity of the product purchased, including the total milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine contained in the product.

(3) The date and time of the purchase.

(4) The name or unique identification of the pharmacist or pharmacist-intern who approved the dispensing of the product.

b. Record format. The record shall be maintained using one of the following options:

(1) A hard-copy record maintained in a bound logbook (i.e., with pages sewn or glued to the spine).

(2) A record in the pharmacy's electronic prescription dispensing record-keeping system.

(3) A record in an electronic data collection system that captures each of the data elements required by this subrule. The electronic data collection system shall be capable of producing a hard-copy printout of a record upon request by the board or its representative or to such other persons or governmental agencies authorized by law to receive such information.

10.32(7) *Notice required.* The following notice shall be included in the logbook required pursuant to subrule 10.32(6) or shall be displayed in the dispensing area and be visible to the public:

"WARNING: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an individual or $500,000 if an organization, imprisoned not more than five years, or both."

657—10.33(124,155A) Schedule II perpetual inventory in pharmacy. Each pharmacy located in Iowa that dispenses Schedule II controlled substances shall maintain a perpetual inventory system for all Schedule II controlled substances pursuant to the requirements of this rule. All records relating to the perpetual inventory shall be maintained by the pharmacy and shall be available for inspection and copying by the board or its representative for a period of two years from the date of the record.

10.33(1) *Record format.* The perpetual inventory record may be maintained in a manual or an electronic record format. Any electronic record shall provide for hard-copy printout of all transactions recorded in the perpetual inventory record for any specified period of time and shall state the current inventory quantities of each drug at the time the record is printed.

10.33(2) *Information included.* The perpetual inventory record shall identify all receipts for and disbursements of Schedule II controlled substances by drug or by national drug code (NDC) number. The record shall be updated to identify each prescription filled and each shipment received. The record shall also include incident reports and reconciliation records pursuant to subrules 10.33(3) and 10.33(4).

10.33(3) *Changes to a record.* If a perpetual inventory record is able to be changed, the individual making a change to the record shall complete an incident report documenting the change. The incident report shall identify the specific information that was changed including the information before and after the change, shall identify the individual making the change, and shall include the date and the reason the record was changed. If the electronic record system documents within the perpetual inventory record all of the information that must be included in an incident report, a separate report is not required.

10.33(4) *Reconciliation.* The pharmacist in charge shall be responsible for reconciling the physical inventory of all Schedule II controlled substances with the perpetual inventory balance on a periodic basis but no less frequently than annually. In case of any discrepancies between the physical inventory and the perpetual inventory, the pharmacist in charge shall determine the need for further investigation, and significant discrepancies shall be reported to the board pursuant to rule 10.16(124) and to the DEA pursuant to federal DEA regulations. Periodic reconciliation records shall be maintained and available for review and copying by the board or agents of the board for a period of two years from the date of the record. The reconciliation process may be completed using either of the following procedures or a combination thereof:

a. The dispensing pharmacist verifies that the physical inventory matches the perpetual inventory following each dispensing and documents that reconciliation in the perpetual inventory record. If controlled substances are maintained on the patient care unit, the nurse or other responsible licensed health care provider verifies that the physical inventory matches the perpetual inventory following each dispensing and documents that reconciliation in the perpetual inventory record. All discrepancies shall be reported to the pharmacist in charge. If any Schedule II controlled substances in the pharmacy's current inventory have been dispensed and verified in this manner within the year, and there are no discrepancies noted, no additional reconciliation action is required. A drug that has had no activity within the year shall be reconciled pursuant to paragraph *"b"* of this subrule.

b. A physical count of each Schedule II controlled substance stocked by the pharmacy shall be completed at least once each year, and that count shall be reconciled with the perpetual inventory record balance. The physical count and reconciliation may be completed over a period of time not to exceed one year in a manner that ensures that the perpetual inventory and the physical inventory of Schedule II controlled substances are annually reconciled. The individual performing the reconciliation shall record the date, the time, the individual's initials or unique identification, and any discrepancies between the physical inventory and the perpetual inventory. Any discrepancies between the physical inventory and the perpetual inventory shall be reported to the pharmacist in charge.

657—10.34(124,155A) Records. Every inventory or other record required to be kept under this chapter or under Iowa Code chapter 124 shall be kept by the registrant and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record except as otherwise required in these rules. Controlled substances records shall be maintained in a readily retrievable manner that establishes the receipt and distribution of all controlled substances.

10.34(1) *Schedule I and II records.* Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the registrant.

10.34(2) *Schedule III, IV, and V records.* Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the required information is readily retrievable from the ordinary business records of the registrant.

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

10.34(4) *Receipt and disbursement records.* Each record of receipt or disbursement of controlled substances, unless otherwise provided in these rules or pursuant to federal law, shall include the following:

a. The name of the substance;

b. The strength and dosage form of the substance;

c. The number of units or commercial containers acquired from other registrants, including the date of receipt and the name, address, and DEA registration number of the registrant from whom the substances were acquired;

d. The number of units or commercial containers distributed to other registrants, including the date of distribution and the name, address, and DEA registration number of the registrant to whom the substances were distributed; and

e. The number of units or commercial containers disposed of in any other manner, including the date and manner of disposal and the name, address, and DEA registration number of the registrant to whom the substances were distributed for disposal, if appropriate.

10.34(5) *Dispensing records.* Each record of dispensing of controlled substances to a patient or research subject shall include the following information:

a. The name and address of the person to whom dispensed;

b. The date of dispensing;

c. The name of the substance;

d. The quantity of the substance dispensed; and

e. The name or unique identification of the individual who dispensed or administered the substance.

10.34(6) *Ordering or distributing Schedule I or II controlled substances - DEA Form 222.* Except as otherwise provided by subrule 10.34(7) and under federal law, a DEA Form 222 is required for each distribution of a Schedule I or II controlled substance. An order form may be executed only on behalf of the registrant named on the order form and only if the registrant's DEA and Iowa registrations for the substances being purchased have not expired or been revoked or suspended by the issuing agency.

a. Order forms shall be obtained, executed, and filled pursuant to DEA requirements. Each form shall be complete, legible, and properly prepared, executed, and endorsed and shall contain no alteration, erasure, or change of any kind.

b. The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier.

c. The purchaser shall maintain Copy 3 of the order form in the files of the registrant. Upon receipt of the substances from the supplier, the purchaser shall record on Copy 3 of the order form the quantity of each substance received, and the date of receipt, and shall initial each line identifying a substance received.

d. The supplier shall record on Copy 1 and Copy 2 of the order form the quantity of each substance distributed to the purchaser and the date on which the shipment is made. The supplier shall maintain Copy 1 of the order form in the files of the supplier and shall forward Copy 2 of the order form to the DEA district office.

e. Order forms shall be maintained separately from all other records of the registrant.

f. Each unaccepted, defective, or otherwise "void" order form and any attached statement or other documents relating to any order form shall be maintained in the files of the registrant.

g. If the registration of any purchaser of Schedule I or II controlled substances is terminated for any reason, or if the name or address of the registrant as shown on the registration is changed, the registrant shall return all unused order forms to the DEA district office.

10.34(7) *Ordering or distributing Schedule I or II controlled substances - electronic ordering system.* A registrant authorized to order or distribute Schedule I or II controlled substances via the DEA Controlled Substances Ordering System (CSOS) shall comply with the requirements of the DEA relating to that system, including the maintenance and security of digital certificates, signatures, and passwords and all record-keeping and reporting requirements.

a. For an electronic order to be valid, the purchaser shall sign the electronic order with a digital signature issued to the purchaser or the purchaser's agent by the DEA.

b. An electronic order may include controlled substances that are not in Schedules I and II and may also include noncontrolled substances.

c. A purchaser shall submit an order to a specific wholesale distributor appropriately licensed to distribute in Iowa.

d. Prior to filling an order, a supplier shall verify the integrity of the signature and the order, verify that the digital certificate has not expired, check the validity of the certificate, and verify the registrant's authority to order the controlled substances.

e. The supplier shall retain an electronic record of every order, including a record of the number of commercial or bulk containers furnished for each item and the date on which the supplier shipped the containers to the purchaser. The shipping record shall be linked to the electronic record of the

order. Unless otherwise provided under federal law, a supplier shall ship the controlled substances to the registered location associated with the digital certificate used to sign the order.

f. If an order cannot be filled for any reason, the supplier shall notify the purchaser and provide a statement as to the reason the order cannot be filled. When a purchaser receives such a statement from a supplier, the purchaser shall electronically link the statement of nonacceptance to the original electronic order. Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

g. When a purchaser receives a shipment, the purchaser shall create a record of the quantity of each item received and the date received. The record shall be electronically linked to the original order and shall identify the individual reconciling the order. A purchaser shall, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser shall also retain all copies of each unfilled or defective order and each linked statement.

h. A supplier shall retain each original order filled and all linked records for two years. A supplier shall, for each electronic order filled, forward to the DEA within two business days either a copy of the electronic order or an electronic report of the order in a format specified by the DEA.

i. Records of CSOS electronic orders and all linked records shall be maintained by a supplier and a purchaser for two years following the date of shipment or receipt, respectively. Records may be maintained electronically or in hard-copy format. Records that are maintained electronically shall be readily retrievable from all other records, shall be easily readable or easily rendered into a readable format, shall be readily retrievable at the registered location, and shall be made available to the board, to the board's agents, or to the DEA upon request. Records maintained in hard-copy format shall be maintained in the same manner as DEA Form 222.

657—10.35(124,155A) Physical count and record of inventory. Responsibility for ensuring that a required inventory is timely completed shall rest with the registrant or, in the case of a registered business, shall rest with the owner of the business. A registrant or owner of a registered business may delegate the actual taking of any inventory. The person or persons responsible for taking the inventory shall sign the completed inventory record.

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. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date and at the time the inventory is taken.

b. Each inventory shall be maintained in a handwritten, typewritten, or electronically printed form at the registered location. An inventory of Schedule II controlled substances shall be maintained separately from an inventory of all other controlled substances.

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.

d. A separate inventory shall be made for each registered location and for each independent activity registered except as otherwise provided under federal law.

e. The inventory shall be taken either prior to opening or following the close of business on the inventory date, and the inventory record shall identify either opening or close of business.

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.

g. For all substances listed in Schedule I or II, and for all solid oral and injectable hydrocodone-containing products, the quantity shall be an exact count or measure of the substance.

h. For all substances listed in Schedule III, IV, or V, except for hydrocodone-containing products identified in paragraph *"g"* herein, the quantity may be an estimated count or measure of the substance unless the container has been opened and originally held more than 100 dosage units. If the opened commercial container originally held more than 100 dosage units, an exact count of the contents shall be made. Liquid oral hydrocodone-containing products packaged in incremented containers shall be measured to the nearest increment; products packaged in nonincremented containers may be estimated to the nearest one-fourth container.

10.35(2) *Initial inventory.* A new registrant shall take an inventory of all stocks of controlled substances on hand on the date the new registrant first engages in the manufacture, distribution, or dispensing of controlled substances. If the registrant commences business or the registered activity with no controlled substances on hand, the initial inventory shall record that fact.

10.35(3) *Annual inventory.* After the initial inventory is taken, a registrant shall take a new inventory of all stocks of controlled substances on hand at least annually. The annual inventory may be taken on any date that is within one year of the previous inventory date.

10.35(4) *Change of ownership.* Both the current owner and the prospective owner shall be responsible for ensuring that an inventory of all controlled substances is timely completed whenever there is a change of ownership of any pharmacy or drug wholesaler licensed pursuant to Iowa Code section 155A.13 or 155A.17, respectively.

10.35(5) *Change of pharmacist in charge (PIC).* An inventory of all controlled substances shall be completed whenever there is a change of PIC. The inventory shall be taken following the close of business the last day of the terminating PIC's employment and prior to opening for business the first day of the new PIC's employment. A single inventory shall be sufficient if there is no lapse between employment of the terminating PIC and the new PIC.

10.35(6) *Change of registered location.* A registrant shall take an inventory of all controlled substances whenever there is a change of registered location. The inventory shall be taken following the close of business the last day at the location being vacated. This inventory shall serve as the ending inventory for the location being vacated as well as a record of beginning inventory for the new location.

10.35(7) *Discontinuing registered activity.* A registrant shall take an inventory of controlled substances at the close of business the last day the registrant is engaged in registered activities. If the registrant is selling or transferring the remaining controlled substances to another registrant, this inventory shall serve as the ending inventory for the registrant discontinuing business as well as a record of additional or starting inventory for the registrant to whom the substances are transferred.

10.35(8) *Newly controlled substances.* On the effective date of the addition of a previously noncontrolled substance to any schedule of controlled substances, any registrant who possesses the newly controlled substance shall take an inventory of all stocks of the substance on hand. That initial inventory record shall be maintained with the most recent controlled substances inventory record. Thereafter, the newly controlled substance shall be included in each inventory made by the registrant.

657—10.36(124) Samples and other complimentary packages—records. Complimentary packages and samples of controlled substances may be distributed to practitioners pursuant to federal and state law only if the person distributing the items leaves with the practitioner a specific written list of the items delivered.

10.36(1) *Distribution record.* The record form for the distribution of complimentary packages of controlled substances shall contain the following information:

a. The name, address, and DEA registration number of the supplier;

b. The name, address, and DEA registration number of the practitioner;

c. The name, strength, and quantity of the specific controlled substances delivered; and

d. The date of delivery.

10.36(2) *Reports to the board.* Any person who distributes controlled substances pursuant to this rule shall report all such distributions to the board. Reports shall:

a. Include the information identified in subrule 10.36(1). Reports may consist of copies of those distribution records or may be computer-generated listings identifying those distributions.

b. Be submitted as soon as practicable after distribution to the practitioner but no less often than once each calendar quarter.

10.36(3) *Practitioner records.* A practitioner who regularly administers or dispenses controlled substances shall keep records of the receipt and disbursement of such drugs, including complimentary packages and samples. Records shall be filed in a readily retrievable manner in accordance with federal requirements and shall be made available for inspection and copying by agents of the board or other authorized individuals for at least two years from the date of the record.

657—10.37(124,126) Revision of controlled substances schedules.

10.37(1) *Application for exception.* Any person seeking to have any compound, mixture, or preparation containing any depressant or stimulant substance listed in any of the schedules in Iowa Code chapter 124 excepted from the application of all or any part of that chapter may apply to the board for such exception.

a. An application for an exception under this rule shall provide evidence that an exception has been granted under the federal Controlled Substances Act.

b. The board shall permit any interested person to file written comments on or objections to the proposal for exception and shall designate the time during which such filings may be made. After consideration of the application and any comments on or objections to the proposal for exception, the board shall issue its findings on the application.

10.37(2) *Designation of new controlled substance.* The board may designate any new substance as a controlled substance to be included in any of the schedules in Iowa Code chapter 124 no sooner than 30 days following publication in the Federal Register of a final order so designating the substance under federal law. Designation of a new controlled substance under this subrule shall be temporary as provided in Iowa Code section 124.201, subsection 4.

10.37(3) *Objection to designation of a new controlled substance.* The board may object to the designation of any new substance as a controlled substance within 30 days following publication in the Federal Register of a final order so designating the substance under federal law. The board shall file objection to the designation of a substance as controlled, shall afford all interested parties an opportunity to be heard, and shall issue the board's decision on the new designation as provided in Iowa Code section 124.201, subsection 4.

657—10.38(124) Temporary designation of controlled substances.

10.38(1) Amend Iowa Code section 124.206, subsection 3, by adding the following new paragraph:

ab. Tapentadol.

10.38(2) Amend Iowa Code section 124.212, subsection 5, as follows:

5. Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substance having a depressant effect on the central nervous system, including its salts: ~~pregabalin~~

a. Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide].

b. Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid].

[**ARC 7906B**, IAB 7/1/09, effective 6/22/09]

657—10.39(124,126) Excluded substances. The Iowa board of pharmacy hereby excludes from all schedules the current list of "Excluded Nonnarcotic Products" identified in Title 21, CFR Part 1308, Section 22. Copies of the list of excluded products may be obtained by written request to the board office at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

657—10.40(124,126) Anabolic steroid defined. Anabolic steroid, as defined in Iowa Code section 126.2, paragraph 2, includes any substance identified as such in Iowa Code section 124.208, paragraph 6, or in Iowa Code section 126.2, paragraph 2.

These rules are intended to implement Iowa Code sections 124.201, 124.301 to 124.308, 124.402, 124.403, 124.501, 126.2, 126.11, 147.88, 147.95, 147.99, 155A.13, 155A.17, 155A.26, 155A.37, and 205.3.

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CHAPTER 11
DRUGS IN EMERGENCY MEDICAL SERVICE PROGRAMS

[Prior to 2/10/88, see Pharmacy Examiners[620] Ch 11]

657—11.1(124,147A,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Ambulance service" means any privately or publicly owned service program that utilizes ambulances in order to provide patient transportation and emergency medical services.

"Board" means the Iowa board of pharmacy examiners.

"Department" means the Iowa department of public health.

"Drug" means a substance as defined in Iowa Code section 155A.3(13) or a device as defined in Iowa Code section 155A.3(10).

"Emergency medical care personnel" or *"provider"* means an individual who has been trained to provide emergency and nonemergency medical care at the first-responder, EMT-basic, EMT-intermediate, EMT-paramedic, paramedic specialist level, or other certification levels adopted by rule by the department and who has been issued a certificate by the department.

"Emergency medical technician" means any emergency medical technician or EMT as defined in 641—132.1(147A).

"EMS" means emergency medical services.

"Medical director" means any physician licensed under Iowa Code chapter 148, 150, or 150A who shall be responsible for overall medical direction of the service program and who has completed a medical director workshop, sponsored by the department, within one year of assuming duties.

"Physician" means any individual licensed under Iowa Code chapter 148, 150, or 150A.

"Physician assistant" means any individual licensed under Iowa Code chapter 148C.

"Physician designee" means any registered nurse licensed under Iowa Code chapter 152, or any physician assistant licensed under Iowa Code chapter 148C and approved by the board of physician assistant examiners. The physician designee acts as an intermediary for a supervising physician in accordance with written policies and protocols in directing the actions of emergency medical care personnel providing emergency medical services.

"Responsible individual" means, in a medical director-based service, the medical director for the service; in a pharmacy-based service, the pharmacist in charge of the base pharmacy.

"Service" or *"service program"* means any medical care ambulance service or nontransport service that has received authorization by the department.

"Supervising physician" means any physician licensed under Iowa Code chapter 148, 150, or 150A. The supervising physician is responsible for medical direction of emergency medical care personnel when such personnel are providing emergency medical care.

657—11.2(124,147A,155A) Ownership of drugs—options. Ownership of any and all drugs used by an emergency medical service shall be maintained under one of the following options:

11.2(1) *Pharmacy-based services.* Any and all drugs shall be provided by a licensed pharmacy. Under this arrangement, all drugs shall remain the property of the pharmacy. For purposes of this chapter and unless otherwise noted, the pharmacist in charge of the base pharmacy shall be the responsible individual for the service program.

a. A formal written agreement shall be made between the base pharmacy and the service establishing that the EMS is operating as an extension of the base pharmacy with respect to the drugs. The service contract may provide for payment by the service to the pharmacy of reasonable fees or charges.

b. Pharmacies shall provide drugs limited to the drugs listed in the service program's written protocols.

11.2(2) *Medical director-based services.* Any and all drugs shall be provided by the medical director. Under this arrangement, all drugs shall remain the property of the medical director. For purposes of this

chapter and unless otherwise noted, the medical director shall be the responsible individual for the service program.

Whenever necessary and appropriate, the medical director may consult with a pharmacist in regard to all matters relating to the proper use, storage, and handling of drugs and intravenous infusion products which may be administered to patients of the service program.

657—11.3(124,147A,155A) General requirements.

11.3(1) *Exchange program.* Any pharmacy may replace drugs, including controlled substances, which have been administered to patients upon receipt of an order issued by a physician, physician assistant, or physician designee so authorized.

11.3(2) *Controlled substance prescribing.* Controlled substances shall be prescribed only by a person who is so authorized by state law.

11.3(3) *Controlled substance disposal or destruction.* The disposal or destruction of the unused portion of a controlled substance shall be documented in writing and signed by the paramedic or paramedic specialist responsible for administration of the controlled substance and witnessed by one of the emergency service program personnel or a licensed health care professional. Outdated or unwanted controlled substances shall be returned to the service base for proper disposal or destruction.

11.3(4) *Administration of drugs and intravenous infusion products.* An appropriately certified EMS provider shall not administer a drug or intravenous infusion product without the verbal or written order of a physician, physician assistant, or physician designee, or by written protocol. The service program's responsible individual shall be responsible for ensuring proper documentation of orders given and drugs administered.

11.3(5) *Drug control policies and procedures.* The service program's responsible individual shall ensure that written drug and intravenous infusion product security and control policies and procedures are developed and implemented for the service. The policies and procedures shall address, but not be limited to, the following:

a. Controlled substances;
b. Medication orders;
c. Adverse drug and intravenous infusion product reaction reports;
d. Drug and intravenous infusion product administration;
e. Drug and intravenous infusion product defect reports and product recalls;
f. Outdated or unused drugs and intravenous infusion products and their timely disposal;
g. Drug and intravenous infusion product inventory control and security;
h. Record keeping;
i. Drug and intravenous infusion product procurement, storage, and ownership;
j. Inspections and frequency of inspections;
k. Drug exchange programs.

657—11.4(124,147A,155A) Procurement and storage. The responsible individual for the service shall be responsible for the procurement and storage of drugs and intravenous infusion products for the service program.

11.4(1) *Temperature.* All drugs and intravenous infusion products shall be stored at the proper temperatures as defined by the USP/NF.

11.4(2) *Expiration.* Any drug or intravenous infusion product bearing an expiration date may not be administered after the expiration date.

11.4(3) *Outdates.* Outdated drugs and intravenous infusion products shall be quarantined together until such time as the items can be disposed of lawfully.

657—11.5(124,147A,155A) Records. The responsible individual shall ensure that every inventory or other record required to be kept under Iowa Code chapter 124 or 155A and board rules is maintained by the service program and available for inspection and copying by the board or its representative for

at least two years from the date of such inventory or record. Controlled substances inventories shall be maintained for at least four years from the date of the inventory.

657—11.6(124,147A,155A) Inspections.

11.6(1) *Inspection by program's responsible individual.* The responsible individual for the service program shall ensure proper inspection on a periodic basis of the drugs and intravenous infusion products used by the service. Proof of periodic inspection shall be in writing and made available upon request of the board or department.

11.6(2) *Inspection by regulatory agencies.* Drugs and intravenous infusion products used by the service program, as well as records maintained by the responsible individual or service program, shall be subject to inspection and audit by the board. Controlled substances and controlled substances records shall also be subject to inspection and audit by the federal Drug Enforcement Administration.

657—11.7(124,147A,155A) Security and control. The responsible individual for the service program shall ensure that the program's policies and procedures provide for adequate safeguards against theft or diversion of prescription drugs or devices, controlled substances, and records for such drugs and devices. The following conditions must be met to ensure appropriate control over drugs and intravenous infusion products.

11.7(1) *Access authorized.* Policies and procedures shall identify who will have access to the drugs and intravenous infusion products.

11.7(2) *Limited access.* Drugs and intravenous infusion products shall be secured at all times in a manner that limits access to authorized personnel only.

These rules are intended to implement Iowa Code chapter 147A and Iowa Code sections 124.301 and 155A.13.

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CHAPTER 12
PRECURSOR SUBSTANCES

657—12.1(124B) Precursor substance identified. For the purpose of this chapter, precursor substance includes all substances identified in Iowa Code section 124B.2. Additional precursor substances may be identified by listing in this rule.

657—12.2(124B) Reports required. Except as provided in rule 12.4(124B) or 12.5(124B), the following reports shall be filed with the board on forms provided or approved by the board. Copies of reports submitted pursuant to this rule shall be maintained for two years following the date of the report.

12.2(1) *Delivery in Iowa.* Any manufacturer, retailer, or other person who sells, transfers, or otherwise furnishes a precursor substance to anyone within this state shall report the transaction to the board no less than 21 days prior to delivery of the substance.

12.2(2) *Receipt from out-of-state source.* Any vendor, recipient, or other person who receives a precursor substance from a source outside the state shall submit to the board a report of the transaction no more than 14 days following receipt of the substance.

12.2(3) *Missing quantity.* Any vendor, recipient, or other person who is authorized to possess precursor substances in this state shall report to the board within seven days of discovering either of the following occurrences:

a. Loss or theft of a precursor substance.

b. A difference between the amount of a precursor substance shipped and the amount of a precursor substance received.

657—12.3(124B) Form of reports. All reports shall be on forms provided by the board except as provided in rule 12.4(124B). The following minimum information shall be completed for each required report.

12.3(1) *Delivery.* Each form that reports the sale, transfer, or other furnishing of a precursor substance shall contain the following information:

a. Name of substance;

b. Quantity of substance;

c. Date sold, transferred, or furnished;

d. Name and address of business or person selling, transferring, or furnishing the substance;

e. The signature of the person or the signature of an officer, authorized agent, or authorized employee of the business selling, transferring, or furnishing the substance;

f. Name, address, and identification information of the person or business purchasing or receiving the substance.

12.3(2) *Receipt.* Each form that reports the receipt of a precursor substance shall contain the following information:

a. Name of substance;

b. Quantity of substance;

c. Date received;

d. Name and address of person or business receiving the substance;

e. The signature of the person or the signature of an officer, authorized agent, or authorized employee of a business receiving the substance;

f. Name and address of the person or business selling, transferring, or furnishing the substance.

12.3(3) *Theft or loss.* Each form that reports a missing quantity of a precursor substance shall contain the following information:

a. Name of missing substance;

b. Quantity of substance missing;

c. Date on which the substance was discovered to be missing;

d. Name and address of the person or business reporting the missing quantity;

e. The permit number of the person or business reporting the missing quantity, if applicable;

f. The signature of the person or an officer, authorized agent, or authorized employee of the business reporting the missing quantity;

g. The name and address of the person who transported the precursor substance and the date of shipment, if applicable.

657—12.4(124B) Monthly reporting option.

12.4(1) *Regular repeated deliveries.* Vendors who regularly transfer the same precursor substance to the same recipient may apply to the board for authorization to submit the report of those transactions on a monthly basis. Requests for monthly reporting authorization must be received at the board office at least 21 days prior to the board meeting at which the request will be considered. The board will review each request to determine if the requirements of Iowa Code chapter 124B are met and will notify the vendor of its decision and the reporting format that will be authorized.

12.4(2) *Computer-generated reports.* Vendors may also petition the board to accept reports on a computer-generated basis. If approved, reports may be furnished in hard copy or in board-approved data storage format. The vendor will be responsible for the accuracy of all reports and the prompt correction of any data entry or transmission errors.

12.4(3) *Authorization rescinded at board's discretion.* Authorization to report monthly or to use computer-generated reporting may be rescinded at the board's discretion and with 30 days' advance notice.

657—12.5(124B) Exemptions. The following are exempt from the reporting requirements of subrules 12.2(1), 12.2(2), 12.3(1), and 12.3(2) and the identification requirements of rule 12.6(124B):

1. A licensed pharmacist or other person authorized under Iowa Code chapter 155A to sell or furnish a precursor substance upon the prescription of a practitioner.
2. A practitioner who administers or furnishes a precursor substance to a patient.
3. A manufacturer, wholesaler, retailer, or person who holds a permit issued by the board and who sells, transfers, or otherwise furnishes a precursor substance to a practitioner or pharmacy as defined in Iowa Code section 155A.3.
4. Any retailer or person who sells, transfers, furnishes, or receives a drug containing ephedrine, phenylpropanolamine, or pseudoephedrine or a cosmetic containing a precursor substance if the drug or cosmetic is lawfully sold, transferred, or furnished over the counter without a prescription in accordance with Iowa Code chapter 126.

657—12.6(124B) Identification of purchaser or other recipient. Prior to selling, transferring, or otherwise furnishing in this state any precursor substance as defined in rule 12.1(124B), a vendor shall require appropriate identification of any purchaser or other recipient. Letters and other documentation required by this rule shall be maintained for two years following delivery.

12.6(1) *Face-to-face transactions.* Prior to furnishing any precursor substance in any face-to-face transaction, a vendor shall require and document all of the following:

a. A valid driver's license or other state-issued identification issued to the purchaser's representative. The identification shall contain the photograph and residential or mailing address, other than a post office box number, of the purchaser's representative.

b. The motor vehicle license number of the vehicle owned or operated by the purchaser or the purchaser's representative.

c. A letter of authorization from the purchaser. The letter shall include the purchaser's business license number and business address, a description that identifies how the substance will be used, the name of the purchaser's representative authorized to receive the substance, and the purchaser's signature. The purchaser's representative shall also sign the letter in the presence of the vendor and the vendor shall sign as a witness to the identification and signature of the purchaser's representative.

12.6(2) *Furnishing to a person via transaction not face to face.* Prior to furnishing any precursor substance to a person in a transaction that is not face to face, a vendor shall require a letter of authorization that includes all of the following:

a. The name of the person to whom the substance is to be delivered;
b. The person's residential or mailing address, other than a post office box number;
c. The person's residential telephone number, including area code;
d. The person's place of employment including employer's address and telephone number;
e. The person's date of birth;
f. The person's place of birth;
g. The person's social security number;
h. The person's signature;
i. A description that identifies how the substance will be used.

12.6(3) *Furnishing to a business via transaction not face to face.* Prior to furnishing any precursor substance to a business in a transaction that is not face to face, a vendor shall require a letter of authorization that includes all of the following:

a. The name of the business;
b. The business license number;
c. The business address and telephone number, including area code;
d. A description that identifies how the substance will be used;
e. The signature of an officer, authorized agent, or authorized employee of the business;
f. The typed or printed name and title of the signatory.

657—12.7(124B) Permits. Persons or entities in this state that purchase, transfer, or otherwise receive a precursor substance as defined in rule 12.1(124B) from a source outside the state shall obtain a permit from the board. No person or entity required to obtain a permit shall receive a precursor substance from a source outside the state until an application for permit is approved and the board has issued a permit certificate. Permits shall expire on the last day of the calendar year in which the permit is issued.

12.7(1) *Applications.* Application forms may be obtained from and completed applications shall be submitted to the Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Permit renewal forms will be mailed to each current permit holder approximately 60 days before the expiration date of the permit. A permit holder who has not received a renewal form 45 days prior to expiration of a current permit is responsible for contacting the board to request an application for renewal.

a. Application shall be made on forms provided or approved by the board. Each application shall include all requested information, unless the item is not applicable, in which case that fact shall be indicated.

b. Each application, attachment, or other document filed as part of an application shall be signed by the applicant as follows:

(1) If the applicant is an individual, signature shall be by that individual.
(2) If the applicant is a partnership, signature shall be by a partner.
(3) If the applicant is a corporation, corporate division, association, trust, or other entity, signature shall be by the chief executive officer.

12.7(2) *Initial permit, renewal, and fees.* The fee for an initial permit or permit renewal shall be paid at the time that the application for the permit or permit renewal is submitted for filing. Payment shall be made in the form of a personal, business, certified, or cashier's check or money order made payable to the Iowa Board of Pharmacy. Payments made in the form of foreign currency or third-party endorsed checks will not be accepted.

a. Initial and renewal fees. For each initial permit or timely renewed permit, an applicant shall pay a fee of $200.

b. Late application. Failure to renew a permit prior to January 1 following the permit's expiration shall require payment of the renewal fee plus a $200 late payment fee.

c. Delinquent permit. If a permit is not renewed before its expiration date, the permit is delinquent and the permit holder may not receive a precursor substance from a source outside the state until the delinquent permit is renewed. A delinquent-permit holder that continues activities for which a permit is required may be subject to disciplinary sanctions pursuant to 657—subrule 36.1(4).

12.7(3) *Exemption from permit fee.* The requirement for permit fee is waived for federal, state, and local law enforcement agencies and analytical laboratories. Exemption from payment of permit fees as provided in this subrule does not relieve the agency or laboratory of any requirement to obtain a permit nor of any other requirements or duties prescribed by law.

12.7(4) *Exemption from permit.* A permit is not required for a vendor of a drug containing ephedrine, phenylpropanolamine, or pseudoephedrine or of a cosmetic that contains a precursor substance if the drug or cosmetic is lawfully sold, transferred, or furnished either over the counter without a prescription pursuant to Iowa Code chapter 126 or with a prescription pursuant to Iowa Code chapter 155A.

12.7(5) *Termination.* A permit issued to an individual shall terminate upon the death of the individual. A permit issued to an individual or business shall terminate when the individual or business ceases legal existence, discontinues business, or discontinues activities for which the permit was issued.

657—12.8(124B) Denial, modification, suspension, or revocation of permit. Pursuant to 657—Chapters 35 and 36, the board may deny, suspend, revoke, or modify any permit for any period of time it determines to be justified upon the facts of the case for any violation of this chapter or Iowa Code chapter 124B.

These rules are intended to implement Iowa Code chapter 124B.

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CHAPTER 13
STERILE COMPOUNDING PRACTICES

657—13.1(124,126,155A) Purpose and scope. These rules establish standards and procedures for the preparation, labeling, and distribution of sterile preparations by licensed pharmacies pursuant to a practitioner's order or prescription; for sterile product quality and characteristics; for personnel training, environmental quality, and equipment standards; and for pharmaceutical care. Sterile compounding differs from nonsterile compounding primarily by requiring the maintenance of sterility when preparations are compounded exclusively with sterile ingredients and components and by requiring the achievement of sterility when preparations are compounded with nonsterile ingredients and components. The standards and procedures outlined in this chapter apply to pharmacy practice when a preparation:

1. Is prepared according to the manufacturer's labeled instructions and requires other manipulations that expose the original contents to potential contamination;
2. Contains nonsterile ingredients or employs nonsterile components or devices that must be sterilized before administration; or
3. Is a biologic, diagnostic, drug, or nutrient that possesses characteristics of either "1" or "2" above and includes, but is not limited to, the following preparations that are required to be sterile when they are administered to patients: baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, and suspensions), aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

Standards and safe practices for the compounding of radioactive preparations are identified in 657—Chapter 16.

657—13.2(124,126,155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Anteroom" or *"ante area"* means an ISO Class 8 or superior area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, preparation labeling, and other high-particulate generating activities.

"Aseptic processing" means a method of preparing pharmaceutical and medical products that involves the separate sterilization of the product and of the package, the transfer of the product into the container, and closure of the container under at least ISO Class 5 conditions and using procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

"Beyond-use date" means the date or time following compounding after which the preparation shall not be stored or transported. The beyond-use date is determined from the date or time compounding of the preparation is completed.

"Biological safety cabinet" or *"BSC"* means a ventilated cabinet having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

"Buffer area" or *"cleanroom"* means a room or area where the primary engineering control device is physically located and in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear is not exceeded for a specified cleanliness class. Activities that occur in the buffer area include the preparation and staging of components and supplies used when sterile preparations are compounded.

"Compounding" means the constitution, reconstitution, combination, dilution, or other process causing a change in the form, composition, or strength of any ingredient or of any other attribute of a product.

"Compounding aseptic isolator" or *"CAI"* means a form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. A CAI is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer

processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbially retentive filter, HEPA minimum.

"Critical site" means a location that includes any component or fluid pathway surfaces or openings, such as vial septa, injection ports, beakers, opened ampoules, and needle hubs, exposed and at risk of direct contact with air, moisture, or touch contamination.

"Hazardous drug" means a pharmaceutical that is antineoplastic, carcinogenic, mutagenic, or teratogenic.

"HEPA" means high efficiency particulate air.

"High-risk preparation" means a sterile preparation that is compounded from nonsterile ingredients; that is compounded with nonsterile components, containers, or equipment and requires terminal sterilization; or that meets the conditions of rule 13.13(155A).

"ISO Class 5" or *"Class 100 condition"* means an atmospheric environment that contains less than 100 particles, 0.5 microns or larger in diameter per cubic foot of air, according to ISO standards.

"ISO Class 7" or *"Class 10,000 condition"* means an atmospheric environment that contains less than 10,000 particles, 0.5 microns or larger in diameter per cubic foot of air, according to ISO standards.

"ISO Class 8" or *"Class 100,000 condition"* means an atmospheric environment that contains less than 100,000 particles, 0.5 microns or larger in diameter per cubic foot of air, according to ISO standards.

"Laminar airflow workbench" or *"LAFW"* means an apparatus designed to provide an ISO Class 5 environment for the preparation of sterile products that uses air circulation in a defined direction that passes through a HEPA filter to remove the initial particles and the particles generated within the controlled environment.

"Low-risk preparation" means a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces or that meets the conditions of rule 13.11(155A).

"Media-fill test" or *"MFT"* means a test used to validate aseptic technique of compounding personnel or of processes and to ensure that the processes used are able to produce sterile product without microbial contamination.

"Medium-risk preparation" means a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces and involves complex or numerous manipulations of a sterile product or that meets the conditions of rule 13.12(155A).

"Multiple-dose container" means a multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives.

"Negative pressure room" means a room that is at a lower pressure compared to adjacent spaces, creating a net airflow into the room.

"Positive pressure room" means a room that is at a higher pressure compared to adjacent spaces, creating a net airflow out of the room.

"Preparation" or *"compounded sterile preparation"* means a sterile drug or nutrient that is compounded in a licensed pharmacy or other health care-related facility pursuant to the order of a licensed prescriber, which preparation may or may not contain sterile products.

"Primary engineering control device" means a device or room that provides an ISO Class 5 environment during the compounding process. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), and compounding aseptic isolators (CAIs).

"Product" means a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA.

"Segregated compounding area" means a designated space, either a demarcated area or room, which is restricted to preparing low-risk preparations with 12-hour or less beyond-use date. A segregated compounding area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for the compounding of sterile preparations and shall be void of activities and materials that are extraneous to sterile compounding.

"Single-dose container" means a single-unit container for articles or preparations intended for parenteral administration only, intended for a single use and labeled as such. Examples include prefilled

syringes, cartridges, fusion-sealed containers, and closure-sealed containers when labeled for a single use or single dose.

"Sterile compounding" means the aseptic processing in a clean air environment of any pharmaceutical preparations that are required to be sterile when they are administered into patient body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues, including by not limited to injections (e.g., colloidal dispersions, emulsions, solutions, and suspensions), aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

657—13.3(155A) Responsibilities.

13.3(1) *Pharmacist.* Each pharmacy shall have a pharmacist responsible for ensuring that:

a. Preparations are accurately identified, measured, diluted, and mixed; and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed.

b. Appropriate cleanliness conditions are maintained, including preservation of the sterile environment during the compounding process.

c. Beyond-use dates are established based on direct testing or extrapolation from reliable literature sources. The pharmacy shall maintain written justification of the chosen beyond-use date or, if a written standard is not available, a maximum 24-hour expiration shall be used.

d. Equipment, apparatus, and devices used to compound a preparation are consistently capable of operating properly and within acceptable tolerance limits.

13.3(2) *In-process checking procedure.* Each pharmacy shall establish a written quality assurance procedure that includes the following in-process checks:

a. Appropriate procedures are followed for measuring, mixing, diluting, purifying, sterilizing, packaging, and labeling of the specific preparation.

b. Packaging selection is appropriate to preserve the sterility and strength of the preparation.

c. All functions performed by nonpharmacists are verified by the pharmacist before the preparation is dispensed to the patient.

13.3(3) *Training documentation.* All personnel involved with compounding, repackaging, or manipulating sterile preparations shall be adequately educated and trained. Training shall include written documentation certifying that compounding personnel are able to adequately complete the following activities:

a. Perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces.

b. Select and appropriately don protective garb.

c. Maintain or achieve sterility of preparations in ISO Class 5 primary engineering control devices.

d. Identify, weigh, and measure ingredients.

e. Manipulate sterile products aseptically, sterilize high-risk preparations, and label preparations.

f. Protect personnel and compounding environments from contamination by hazardous drugs.

657—13.4 Reserved.

657—13.5(155A) References required. The pharmacy shall have sufficient current reference materials related to sterile products and preparations. References may be printed or computer-accessed. In addition to meeting the requirements set forth in rule 657—6.3(155A), 657—7.3(155A), 657—15.4(155A), or 657—16.5(155A), as applicable, all pharmacies involved in sterile compounding shall maintain a minimum of one current reference, including access to current periodic updates, from each of the following categories:

1. A general information reference.
2. An injectable drug compatibility reference.
3. If the pharmacy is compounding hazardous drugs, a reference related to hazardous drugs.

657—13.6(126,155A) Policies and procedures. A written policy and procedure manual shall be prepared, implemented, maintained, and adhered to for the compounding, dispensing, delivery,

administration, storage, and use of sterile preparations. The manual shall establish policies and procedures relating to subjects identified in this and other rules within this chapter.

13.6(1) *Quality assurance program.* The policy and procedure manual shall include a quality assurance program pursuant to rule 13.31(155A).

13.6(2) *Sampling.* The policy and procedure manual shall include procedures that require sampling of a preparation as provided in rule 13.29(126,155A) or if microbial contamination is suspected.

13.6(3) *Preparation recall.* The policy and procedure manual shall include procedures for the recall of dispensed preparations that fail to meet product quality standards.

13.6(4) *Hazardous products and infectious waste.* The policy and procedure manual shall include procedures for proper handling of hazardous drug products and infectious waste, if applicable.

13.6(5) *Periodic review.* The policy and procedure manual shall be periodically reviewed. Policies shall specify the frequency of review. The manual shall be available for inspection and copying by the board or agents of the board.

657—13.7(126,155A) Labeling requirements.

13.7(1) *Patient-specific dispensing container.* At the time of delivery, a patient-specific dispensing container used for a preparation shall bear a label with at least the following information:

a. Name and quantity of all contents.

b. Patient's name.

c. For home care patient prescriptions, unique serial number or prescription number.

d. Preparer's and reviewing pharmacist's initials or unique identifiers.

e. Stability (beyond-use date) as set forth in the pharmacy's policy and procedure manual.

f. The prescribed flow rate in ml/hr, if applicable.

g. Auxiliary labels as needed.

13.7(2) *Batch preparation.* Each container of a batch preparation that is compounded in anticipation of later dispensing shall bear a label with at least the following information:

a. Name and quantity of all contents.

b. Internal code to identify the date and time of preparation and the preparer's and reviewing pharmacist's initials or unique identifiers.

c. Stability (beyond-use date) as set forth in the pharmacy's policy and procedure manual.

d. Auxiliary labels as needed.

657—13.8 and **13.9** Reserved.

657—13.10(126,155A) Microbial contamination risk levels. Preparations shall be assigned an appropriate risk level—low, medium or high—according to the corresponding probability of contaminating a preparation with microbial contamination such as microbial organisms, spores, and endotoxins, and chemical and physical contamination such as foreign chemicals and physical matter. The characteristics described in rules 13.11(155A), 13.12(155A), and 13.13(155A) are intended as guides to the diligence required in compounding at each risk level.

657—13.11(155A) Low-risk preparations and low-risk preparations with 12-hour or less beyond-use date.

13.11(1) *Conditions defined—low-risk preparations.* Preparations compounded under all of the following conditions are at a low risk of contamination.

a. The preparations are compounded with aseptic manipulations entirely within ISO Class 5 or superior air quality using only sterile ingredients, products, components, and devices.

b. The compounding involves only transferring, measuring, and mixing not more than three commercially manufactured packages of sterile products and not more than two entries into any one container (e.g., bag, vial) of sterile product or administration container or device to make the preparation.

c. Manipulations are limited to aseptically opening ampoules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, containers of other sterile products, and containers for storage and dispensing.

d. In the absence of the preparation's passing a sterility test and provided that the preparation is properly stored before administration, storage periods shall not exceed the following:

(1) At controlled room temperature for 48 hours;

(2) At a cold temperature for 14 days; or

(3) In a solid-frozen state between minus 25 and minus 10 degrees Celsius for 45 days.

13.11(2) *Examples—low-risk preparations.* Examples of low-risk compounding include:

a. The single-volume transfer of sterile dosage forms from ampoules, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. When ampoules are employed, solution content shall be passed through a sterile filter to remove any particles.

b. The manual measuring and mixing of no more than three manufactured products including an infusion or diluent solution to compound drug admixtures and nutritional solutions.

13.11(3) *Low-risk preparations with 12-hour or less beyond-use date.* If the primary engineering control device is a CAI and does not meet the requirements described in subrule 13.27(3) or is a BSC or LAFW that cannot be located within an ISO Class 7 buffer area, then only low-risk nonhazardous and radiopharmaceutical preparations compounded pursuant to a prescriber's order for a specific patient may be prepared, and administration of such preparations shall commence within 12 hours of the start of compounding or as recommended in the manufacturers' package insert, whichever is less. Preparations shall meet all four of the following criteria:

a. The primary engineering control device shall be certified and shall maintain ISO Class 5 for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of preparation contamination.

b. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, food preparation areas, or other areas presenting a risk of contamination.

c. Personnel shall be appropriately garbed and shall perform appropriate cleansing activities prior to compounding. Sinks should be separated from the immediate area of the ISO Class 5 primary engineering control device.

d. Appropriate procedures for cleaning and disinfecting the sterile compounding areas, for personnel training and competency evaluation, for aseptic practices and cleaning or disinfecting processes, and for environmental air sampling and testing shall be followed.

657—13.12(155A) Medium-risk preparations.

13.12(1) *Conditions defined.* Preparations compounded aseptically under low-risk conditions with one or more of the following additional conditions are at a medium risk of contamination.

a. Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile preparation for administration either to multiple patients or to one patient on multiple occasions.

b. The compounding process includes complex aseptic manipulations other than the single-volume transfer.

c. The compounding process requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

d. In the absence of the preparation's passing a sterility test and provided that the preparation is properly stored before administration, storage periods shall not exceed the following:

(1) At controlled room temperature for 30 hours;

(2) At a cold temperature for 9 days; or

(3) In a solid-frozen state between minus 25 and minus 10 degrees Celsius for 45 days.

13.12(2) *Examples.* Examples of medium-risk compounding include:

a. Compounding total parenteral nutrition fluids, using manual or automated devices and involving multiple injections, detachments, or attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.

b. Filling reservoirs of injection or infusion devices with more than three sterile drug products and evacuating air from those reservoirs before dispensing the filled device.

c. Transferring volumes from multiple ampoules or vials into one or more final sterile containers.

657—13.13(155A) High-risk preparations.

13.13(1) *Conditions defined.* Preparations that are either contaminated or likely to become contaminated with infectious microorganisms when compounded under any of the following conditions are at a high risk of contamination.

a. Nonsterile ingredients, including manufactured products not intended for sterile use, are incorporated or a nonsterile device is used in the compounding process before terminal sterilization.

b. Sterile contents of commercially manufactured products, preparations that lack effective antimicrobial preservatives, and sterile surfaces of devices and containers intended for the preparation, transfer, sterilization, and packaging of preparations are exposed to air quality inferior to ISO Class 5 for more than one hour.

c. Nonsterile procedures such as weighing and mixing in air quality inferior to ISO Class 7 are performed before sterilization, compounding personnel are not properly garbed and gloved, or nonsterile water-containing preparations are stored for more than six hours.

d. The chemical purity and content strength of bulk ingredients, whether the ingredients are in opened or unopened packages, are not verified by examination of labeling and documentation of suppliers or by direct determination.

e. For a sterilized high-risk preparation, in the absence of the preparation's passing a sterility test, the storage periods shall not exceed the following:

(1) At controlled room temperature for 24 hours;

(2) At a cold temperature for 3 days; or

(3) In a solid-frozen state between minus 25 and minus 10 degrees Celsius for 45 days.

13.13(2) *Examples.* Examples of high-risk compounding include:

a. Dissolving nonsterile bulk drugs or nutrient powders to make solutions that will be terminally sterilized.

b. Measuring and mixing sterile ingredients in nonsterile devices before sterilization is performed.

c. Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95 percent by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

d. Exposing the sterile ingredients and components used to prepare and package the preparation to air quality inferior to ISO Class 5 for more than one hour.

657—13.14(155A) Immediate-use preparations. The immediate-use provisions of this rule are intended only for those situations where there is a need for emergency or immediate administration of a sterile preparation. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the compounding of the preparation under low-risk level conditions would subject the patient to additional risk due to delays in therapy. Immediate-use preparations are not intended for storage for anticipated needs or for batch compounding. Medium-risk and high-risk preparations shall not be compounded as immediate-use preparations. Immediate-use preparations are exempt from the provisions of rule 13.11(155A) for low-risk preparations only when all of the following criteria are met:

1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package of sterile infusion solution or administration container or device. Hazardous drugs shall not be compounded as immediate-use preparations.

2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed one hour.

3. During compounding, aseptic technique is followed and, if the preparation is not immediately administered, the preparation is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other sterile preparations, and direct contact with outside surfaces.

4. Administration begins not later than one hour after compounding of the preparation is completed.

5. If administration has not begun within one hour after compounding of the preparation is completed, the preparation is promptly and safely discarded.

6. Unless immediately and completely administered by the person who compounded the preparation or unless immediate and complete administration is witnessed by the person who compounded the preparation, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who compounded the preparation, and the exact one-hour beyond-use date and time.

657—13.15(155A) Utilization of single-dose and multiple-dose containers. Pharmacies utilizing single-dose and multiple-dose containers in sterile compounding shall comply with the following:

1. Single-dose containers that are opened or needle-punctured shall be used within one hour if opened in air quality conditions inferior to ISO Class 5. Any remaining contents shall be discarded.

2. Single-dose vials that are continuously exposed to ISO Class 5 or cleaner air shall be used within six hours after initial needle puncture.

3. Opened single-dose ampoules shall not be stored for any period of time under any air quality conditions.

4. Multiple-dose containers with antimicrobial preservatives that are entered or opened shall be used within 28 days of initial entry or opening unless otherwise specified by the manufacturer.

5. Multiple-dose and single-dose sterile products shall not be combined for use as multiple-dose applications.

657—13.16(155A) Utilization of proprietary bag and vial systems. Sterility storage and beyond-use times for attached and activated container pairs of drug products for intravascular administration shall follow manufacturers' instructions for handling and storage.

657—13.17 to **13.19** Reserved.

657—13.20(124,155A) Sterile preparation of hazardous drugs. Hazardous drugs shall only be prepared for administration under conditions that protect pharmacy personnel in the preparation area.

13.20(1) *Storage and handling.* Policies and procedures shall identify appropriate storage and handling of hazardous drugs to prevent contamination and personnel exposure.

13.20(2) *Caution labeling and distribution.* Preparations containing hazardous drugs shall be labeled on the primary container and placed in an overwrap bag that is also properly labeled. Prepared doses of dispensed hazardous drugs shall be labeled and distributed in a manner to minimize the risk of accidental rupture of the primary container. Proper labeling shall include any necessary precautions.

13.20(3) *Preparation area.* All hazardous drugs shall be compounded in a vertical flow Class II or Class III biological safety cabinet or in a compounding aseptic isolator containment and control device with biohazard control capabilities.

a. It is preferable for the ISO Class 5 BSC or CAI to be placed in a contained environment, physically separated from other preparation areas, where air pressure is negative and where the ISO Class 5 BSC or CAI is appropriately vented to the outside of the building.

b. If the pharmacy compounds fewer than five preparations per week in a BSC or CAI and uses a closed system vial transfer device to compound the preparations, the BSC or CAI may be located in a positive pressure room.

13.20(4) *Protective apparel.* Personnel compounding hazardous drugs shall wear appropriate protective apparel in accordance with documented procedures. Protective apparel may include

disposable, nonshedding coveralls or gowns with tight cuffs, face masks, eye protection, hair covers, double gloves, and shoe covers.

13.20(5) *Techniques.* Appropriate safety and containment techniques for compounding hazardous drugs shall be used in conjunction with the aseptic techniques required for processing sterile preparations.

13.20(6) *Training required.* All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before personnel prepare or handle hazardous preparations and shall be verified and documented for each person at least annually.

13.20(7) *Waste.* Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements.

13.20(8) *Spills of hazardous drugs.* Written procedures for handling both major and minor spills of hazardous drugs shall be developed, maintained, implemented, and adhered to. The procedures shall be maintained with the policies and procedures required in rule 13.6(155A).

657—13.21 and **13.22** Reserved.

657—13.23(124,155A) Verification of compounding accuracy and sterility. Compounding procedures and sterilization methods used for preparations require planned testing, monitoring, and documentation to demonstrate adherence to environmental quality requirements, personnel practices, and procedures critical to achieving and maintaining sterility. Pharmacist verification of a preparation shall include visual inspection of labeling, physical integrity, and expected appearance, including final fill amount.

657—13.24(124,155A) Sterilization methods. The selected sterilization method employed shall be based on experience and appropriate information sources.

13.24(1) *Presterilization requirements for high-risk preparations.*

a. During all compounding activities that precede terminal sterilization, such as weighing and mixing, compounding personnel shall be garbed and gloved in the same manner as when performing compounding in an ISO Class 5 environment. All presterilization procedures shall be completed in an ISO Class 8 or superior environment.

b. Immediately before use, all nonsterile measuring, mixing, and purifying devices used in the compounding process shall be thoroughly rinsed with sterile, pyrogen-free water, and then thoroughly drained or dried.

13.24(2) *Sterilization methods for high-risk preparations.*

a. Sterilization by filtration. This method of sterilization involves the passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

(1) Sterile filters used to sterile filter preparations shall be pyrogen-free and have a nominal porosity of 0.22 microns. The filter dimensions and liquid material to be sterile filtered shall permit the sterilization process to be completed rapidly without the replacement of the filter during the filtering process.

(2) Compounding personnel shall ascertain that selected filters will achieve sterilization of the specific preparation.

(3) Sterilization by filtration shall be performed entirely within an ISO Class 5 or superior air quality environment.

b. Terminal sterilization. Use of saturated steam under pressure, or autoclaving, is the preferred method to terminally sterilize aqueous preparations.

(1) All materials shall be exposed to steam at 121 degrees Celsius under the recommended pressure and duration, verified by testing the sterility of the finished preparation.

(2) The description of steam sterilization conditions and duration for specific preparations shall be included in written documentation maintained in the compounding facility.

(3) Before or during entry into final containers, all high-risk preparations in solution form that are subjected to terminal steam sterilization shall pass through a filter with nominal porosity not larger than 1.2 microns for removal of particulate matter.

c. Dry heat sterilization. Dry heat sterilization shall be completed in an oven designed for sterilization and shall be used only for those materials that cannot be sterilized by steam. The effectiveness of dry heat sterilization shall be verified using appropriate biological indicators and temperature-sensing devices.

13.24(3) *Records.* Record requirements for high-risk preparations shall include documentation of the following:

a. Lot numbers of nonsterile components used in compounding high-risk preparations.

b. Sterilization records including methods used for each preparation.

13.24(4) *Testing and quarantine requirements.* All high-risk preparations, except those for inhalation and ophthalmic administration, that are prepared in groups of 25 or more identical single-dose containers or in multiple-dose vials for administration to multiple patients, or that are exposed longer than 12 hours at 2 to 8 degrees Celsius or longer than 6 hours at warmer than 8 degrees Celsius before they are sterilized, shall be quarantined and tested to ensure that the preparations are sterile and that they do not contain excessive bacterial endotoxins before they are dispensed or administered.

13.24(5) *Release of preparations prior to receipt of testing results.* If a preparation may be needed before the results of sterility testing have been received, the pharmacy shall have a written procedure requiring daily observation of incubating test specimens and immediate recall of the dispensed preparations when there is any evidence of microbial growth in the test specimens.

[**ARC 7633B**, IAB 3/11/09, effective 4/15/09]

657—13.25(155A) Media-fill testing by personnel. The pharmacy shall develop, maintain, and implement written procedures that include appropriate media-fill testing by personnel authorized to compound preparations. The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required. Tests shall be performed without interruption in an ISO Class 5 environment under conditions that closely simulate the stressful conditions encountered during compounding of the specific risk level preparations for which the test is intended. The pharmacy shall maintain records of media-fill testing performed, and results of testing procedures shall be available to the board or agents of the board. Compounding personnel whose media-fill test vials result in gross microbial colonization shall be immediately reinstructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

13.25(1) *Low-risk MFT procedure.* Each person authorized to compound low-risk preparations shall annually perform an appropriate successful MFT procedure. The following is an example of a low-risk MFT procedure:

1. Using the same sterile 10-ml syringe and vented needle combination, aseptically transferring three sets of four 5-ml aliquots of sterile soybean-casein digest medium into separate sealed, empty, sterile 30-ml clear vials (i.e., four 5-ml aliquots into each of three 30-ml vials);
2. Affixing sterile adhesive seal closures onto the three filled vials;
3. Incubating the vials at temperatures between 25 and 35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before the passage of 14 days.

13.25(2) *Medium-risk MFT procedure.* Each person authorized to compound medium-risk preparations shall annually perform an appropriate successful MFT procedure. The following is an example of a medium-risk MFT procedure:

1. Aseptically transferring six 100-ml aliquots of sterile soybean-casein digest medium by gravity through separate tubing sets into separate evacuated sterile containers;
2. Arranging the six containers as three pairs and using a sterile 10-ml syringe and 18-gauge needle combination to exchange two 5-ml aliquots of medium from one container to the other container in the pair (for example, adding 5-ml aliquot from the first container to the second container in the pair, agitating the second container for 10 seconds, and transferring 5-ml aliquot from the second container back to the first container in the pair; then agitating the first container for 10 seconds and transferring the next 5-ml aliquot from the first container back to the second container in the pair; and repeating the procedure for each pair of containers);

3. Aseptically injecting a 5-ml aliquot of medium from each container into a sealed, empty, sterile 10-ml clear vial using a sterile 10-ml syringe and vented needle. Affixing sterile adhesive seals to the rubber closures on the three filled vials and incubating the vials at temperatures within a range of 20 to 35 degrees Celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before the passage of 14 days.

13.25(3) *High-risk MFT procedure.* Each person authorized to compound high-risk preparations shall semiannually perform an appropriate successful MFT procedure. The following is an example of a high-risk MFT procedure:

1. Dissolving 3 gm of nonsterile commercially available soybean-casein digest medium in 100 ml of nonbacteriostatic water to make a 3 percent solution;
2. Drawing 25 ml of the medium into each of three 30-ml sterile syringes. Transferring 5 ml from each syringe into separate sterile 10-ml vials (these vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation);
3. Under aseptic conditions and using aseptic techniques, affixing a sterile 0.2 micron porosity filter unit and a 20-gauge needle to each syringe. Injecting the next 10 ml from each syringe into three separate 10-ml sterile vials. Repeating the process into three more vials. Labeling all vials, affixing sterile adhesive seals to the closure of the nine vials, and incubating them at temperatures between 25 and 35 degrees Celsius. Inspecting for microbial growth over 14 days. Failure is indicated by visible turbidity in the medium on or before the passage of 14 days.

657—13.26 Reserved.

657—13.27(124,126,155A) Physical environment requirements. The pharmacy shall have a designated area for compounding sterile preparations, with entry restricted to designated personnel. The area shall be used only for sterile compounding. The area shall be structurally isolated from other areas and shall be designed to avoid unnecessary traffic and airflow disturbances. The area shall be of sufficient size to accommodate at least one primary engineering control device and to provide for the storage of drugs and supplies under appropriate temperature, light, moisture, sanitation, ventilation, and security conditions.

13.27(1) *Requirement for primary engineering control device.* The primary engineering control device shall be capable of maintaining at least ISO Class 5 air quality in the area where critical objects are exposed and critical activities are performed. The device shall be capable of maintaining ISO Class 5 air quality during normal activity. A primary engineering control device includes, but is not limited to, a horizontal or vertical laminar airflow workbench or CAI.

13.27(2) *Placement of primary engineering control device.* The primary engineering control device shall be placed in a buffer area where HEPA filters are employed and the air quality is maintained at ISO Class 7. This area shall have cleanable, nonshedding, smooth surfaces; all junctures shall be coved; and all cracks and crevices shall be caulked. The ceiling shall be impervious and hydrophobic. The buffer area shall not contain any drains or sinks. Only the furniture, equipment, supplies and other material required for compounding activities to be performed shall be brought into the room. Such items brought into the room shall be cleaned and disinfected. Placement in buffer areas of objects and devices not essential to the compounding process is dictated by the measured effect of those objects and devices on the required environmental quality of air atmospheres and surfaces.

13.27(3) *Exception for placement of CAI.* The CAI shall be placed in an ISO Class 7 cleanroom unless the CAI meets each of the following conditions:

a. The CAI provides isolation from the room and maintains ISO Class 5 conditions when ingredients, components, and devices are transferred into and out of the CAI during the preparation process.

b. The manufacturer provides documentation verifying that the CAI meets the standard in paragraph *"a"* when the CAI is located in an environment inferior to ISO Class 7.

13.27(4) *Anteroom requirements.* An anteroom or ante area shall be located adjacent to the buffer area and maintained at ISO Class 8 air quality. This area is to be used for unpacking and disinfecting

supplies for storage and for hand sanitizing and gowning. If the sterile preparation area is to be used only for the compounding of low- and medium-risk preparations, the ante area shall be clearly demarcated for the compounding of low- and medium-risk preparations. If the sterile preparation area is to be used for the compounding of high-risk preparations, the ante area shall be physically separated from the buffer area.

13.27(5) *Delayed implementation.* A pharmacy whose sterile compounding area is in substantial compliance with the physical and structural requirements of this rule shall be authorized to engage in the compounding of sterile preparations pursuant to the practice standards established by this chapter and subject to the following:

a. Any pharmacy that commences, on or after July 11, 2007, new construction or remodeling of a pharmacy sterile compounding area shall comply with the physical and structural requirements of this rule.

b. Any pharmacy engaged in the compounding of sterile preparations shall, no later than December 31, 2010, complete any necessary changes or improvements to the sterile compounding area to ensure compliance with the physical and structural requirements of this rule.

657—13.28(155A) Cleaning, maintenance, and supplies. The pharmacy shall have appropriate equipment and supplies and documented procedures for maintaining an environment suitable for the aseptic processing of sterile preparations.

13.28(1) *Supplies and equipment.* Required supplies and equipment shall include, but may not be limited to, the following:

a. Appropriate attire including nonshedding coveralls or gowns, head and facial covers, face masks, appropriate gloves, and shoe covers.

b. A sink with hot and cold running water, with bactericidal soap available for the purpose of hand and forearm scrubs, which shall be located convenient to the area used for compounding sterile preparations but outside the buffer area.

13.28(2) *Documented procedures.* Documented procedures shall include, but not be limited to, the following:

a. Specific cleaning procedures and frequencies for each compounding area involved.

b. Identification of the individual responsible for completing each procedure.

c. A list of approved cleaning agents for each procedure.

d. A written plan and schedule for the evaluation of airborne microorganisms in each controlled air environment (e.g., LAFW, barrier isolators, buffer area, and anteroom).

e. Equipment calibration, annual maintenance, and monitoring of proper function of equipment, apparatus, and devices used to compound sterile preparations.

f. An appropriate cleansing and garbing procedure. Coveralls and gowns may be hung outside the entry in the buffer area and reused for one shift, provided the coveralls and gowns are not visibly soiled and have not been worn during the compounding of hazardous drugs.

657—13.29(126,155A) Environmental monitoring requirements.

13.29(1) *Certification required.* All cleanrooms, laminar airflow workbenches, and barrier isolators shall be certified by an independent contractor according to ISO Standards 14644-1:1999(E) and ISO Standards 14664-3:2005(E), or National Sanitation Foundation Standard 49, for operational efficiency at least every six months and whenever the device or room is relocated or altered or whenever major service to the facility is performed. Inspection and certification records shall be maintained for two years from the date of certification.

13.29(2) *Procedures required.* The pharmacy shall establish written procedures appropriate for the risk level preparations compounded by the pharmacy. The procedures shall include environmental testing, end testing, and evaluation of validation results.

a. Air sampling. Microbial sampling of air within the primary engineering control devices, buffer areas, and anterooms is required at least semiannually as part of the recertification of facilities and

equipment. If compounding occurs in multiple locations within an institution, environmental sampling is required for each individual compounding area.

b. Pressure differential monitoring. A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the anteroom and between the anteroom and the general pharmacy area. The gauge/meter shall alert the pharmacy when air conditions do not meet recommended conditions, and all compounding shall be discontinued until the alarm condition is corrected. If the gauge/meter is incapable of alerting the pharmacy to inappropriate conditions, the pharmacy shall monitor and review the gauge/meter daily and document the results in a log.

657—13.30 Reserved.

657—13.31(155A) Quality assurance (QA). The pharmacy shall establish, implement, and document an ongoing quality assurance program in order to maintain and improve facilities, equipment, personnel performance, and the provision of patient care.

13.31(1) *Physical performance QA.* The portion of the quality assurance program that monitors facilities, equipment, and personnel performance shall include, but need not be limited to, the following:

a. Methods for verification of automated compounding devices for parenteral nutrition compounding.

b. Methods for sampling finished preparations to ensure that the pharmacy is capable of consistently preparing sterile preparations that meet appropriate risk level specifications and to ensure product integrity.

c. Procedures for inspection of all prescription orders, written compounding procedures, preparation records, and materials used to compound at all contamination risk levels, to ensure accuracy of ingredients, aseptic mixing, sterilizing, packaging, labeling, and expected physical appearance of the finished preparation.

d. Procedures for visual inspection of preparations to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

e. Procedures for review of all orders and packages of ingredients to ensure that the correct ingredients and quantity of ingredients were compounded.

f. Methods for routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality.

g. Methods for ensuring personnel qualifications, training, and performance, including periodic performance of applicable MFT procedures.

h. Procedures for visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments.

i. Methods for establishing beyond-use dates of preparations.

13.31(2) *Care outcomes QA.* The portion of the quality assurance program that monitors patient care shall include, but need not be limited to, the following:

a. Utilizing specific procedures for recording, filing, and evaluating reports of adverse events and the quality of preparation identified in the adverse event.

b. Utilizing written policies and procedures that include specific procedures or instructions for receiving, acknowledging, and dating the receipt of products.

c. Reviewing documented patient or caregiver education and training required pursuant to rule 13.32(155A).

d. Ensuring that a qualified pharmacist is available and accessible at all times to respond to the questions and needs of other health professionals, the patient, or the patient's caregiver.

e. Identifying activities and processes that are deemed high-risk, high-volume, or problem-prone and providing effective corrective actions to remedy these activities and processes.

657—13.32(155A) Patient or caregiver education and training. If sterile preparations are provided to the patient in the home environment, the pharmacist, in conjunction with nursing or medical personnel,

shall verify and document the patient's or caregiver's training and competence in managing the type of prescribed therapy.

13.32(1) *Pharmacist involvement.* A pharmacist shall be actively involved in patient training processes relating to drug compounding, labeling, administration, storage, stability, compatibility, or disposal. The pharmacist shall continually reassess the patient's or caregiver's competency in these areas.

13.32(2) *Demonstration and practice.* Training programs shall include hands-on demonstrations and practice with actual items that the patient or caregiver is expected to use in managing the specific type of therapy.

13.32(3) *Additional training tools.* Printed materials and posttraining verbal counseling shall be used periodically, as appropriate, to reinforce initial training programs and to ensure the patient's or caregiver's continuing correct and complete fulfillment of responsibilities.

657—13.33(124,155A) Storage and delivery of sterile preparations. The pharmacy is responsible for proper packaging, handling, transport, and storage of preparations compounded and dispensed by the pharmacy and for appropriate education, training, and supervision of pharmacy and nonpharmacy personnel responsible for such functions. The pharmacy shall establish, maintain, and implement written policies and procedures to ensure product quality and packaging integrity until the preparation is administered.

13.33(1) *Storage areas.* Controlled temperature storage areas within the pharmacy shall be monitored at least once daily and the results documented on a temperature log. Temperature-sensing mechanisms shall be suitably placed within the storage space to accurately reflect the area's temperature.

13.33(2) *Packaging, handling and transport.* Appropriate policies and procedures shall be established, maintained, and implemented by the pharmacy with the involvement of other departments or services whose personnel are responsible for preparation or handling functions outside the pharmacy.

a. Policies and procedures shall include instruction in proper hand washing, aseptic techniques, site care, and change of administration sets to ensure the quality and sterility of the preparation.

b. A pharmacy that compounds or prepares products or devices or uses techniques where in-line filtration, automated infusion control devices, or replenishment of drug products into reservoirs of portable infusion pumps is required shall implement policies and procedures to address the special needs related to those products and techniques.

c. Policies and procedures shall provide for the return to the pharmacy of unused preparations for appropriate disposition. Appropriate disposition may include redispensing only if the continuing quality and sterility of the preparation can be fully ensured. The pharmacy shall be the sole authority for determining whether a preparation that was not administered as originally intended can be used for an alternate patient or under alternate conditions.

d. Policies and procedures regarding the handling of hazardous preparations shall identify safeguards intended to maintain the integrity of the preparations and to minimize the exposure potential of these products to the environment and to personnel who have contact with the products.

These rules are intended to implement Iowa Code sections 124.301, 126.10, 155A.2, 155A.4, 155A.13, 155A.13A, and 155A.28.

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CHAPTER 14
PUBLIC INFORMATION AND INSPECTION OF RECORDS

657—14.1(22,124,155A) Definitions. As used in this chapter:

"Board" means the Iowa board of pharmacy examiners.

"Confidential record" means a record which is not available as a matter of right for examination and copying by members of the public under applicable provisions of law. Confidential records include records or information contained in records that the board is prohibited by law from making available for examination by members of the public, and records or information contained in records that are specified as confidential by Iowa Code section 22.7 or other provision of law, but that may be disclosed upon order of a court, order of the lawful custodian of the record, or order of another person duly authorized to release the record. Mere inclusion in a record of information declared confidential by an applicable provision of law does not necessarily make that entire record a confidential record.

"Custodian" means the executive secretary/director of the board.

"Open record" means a record other than a confidential record.

"Personally identifiable information" means information about or pertaining to an individual or business entity in a record which identifies the individual or entity and which is contained in a record system.

"Record" means the whole or a part of a "public record," as defined in Iowa Code section 22.1, that is owned by or in the physical possession of the board.

"Record system" means any group of records under the control of the board from which a record may be retrieved by a personal identifier such as the name of an individual or business entity, number, symbol, or other unique retriever assigned to an individual or business entity.

657—14.2(22,124,155A) Purpose and scope. The purpose of this chapter is to facilitate broad public access to open records. It seeks to facilitate rational board determinations with respect to the handling of confidential records and the implementation of the fair information practices Act. Board staff shall cooperate with members of the public in implementing the provisions of this chapter.

This chapter does not:

1. Require the board to index or retrieve records that contain information about individuals by that person's name or other personal identifier.
2. Make available to the general public records that would otherwise not be available under Iowa Code chapter 22.
3. Govern the maintenance or disclosure of, notification of or access to records in the possession of the board that are governed by rules of another board or agency.
4. Apply to grantees, including local governments or subdivisions, administering state-funded programs, unless otherwise provided by law or agreement.
5. Make available records compiled by the board in reasonable anticipation of court litigation or formal administrative proceedings. Applicable legal and constitutional principles, statutes, rules of discovery, evidentiary privileges, and rules of the board shall govern the availability of the records to the general public or to any subject individual or party to litigation or proceedings.

657—14.3(22,124,155A) Requests for access to records.

14.3(1) *Location of record.* A request for access to a record should be directed to Executive Secretary/Director, Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

14.3(2) *Office hours.* Open records shall be made available during all customary office hours, which are 8 a.m. to 4:30 p.m. daily, excluding Saturdays, Sundays, and official state holidays.

14.3(3) *Request for access.* Requests for access to open records shall be made in writing. Requests shall identify the particular records sought, by name or description, in order to facilitate determining the location of the record. All requests shall include the name, address, and telephone number of the person requesting the information.

14.3(4) *Response to requests.* Access to an open record shall be provided in a timely manner upon request. If the size or nature of the request for access to an open record requires time for processing, the custodian shall comply with the request as soon as feasible. Access to an open record may be delayed for one of the purposes authorized by Iowa Code section 22.8(4) or 22.10(4). The custodian shall promptly give notice to the requester of the reason for any delay in access to an open record and an estimate of the length of that delay and, upon request, shall promptly provide that notice to the requester in writing.

The custodian of a record may deny access to the record by members of the public only on the grounds that such a denial is warranted under Iowa Code section 22.8(4) or 22.10(4), or that it is a confidential record, or that its disclosure is prohibited by a court order. Access by members of the public to a confidential record is limited by law and, therefore, may generally be provided only in accordance with the provisions of rule 14.4(22,124,155A) and other applicable provisions of law.

14.3(5) *Security of record.* No unauthorized person may search or remove any record from board files. The custodian or a designee of the custodian shall supervise examination and copying of board records. The integrity of board records shall not be compromised during such examination or handling.

14.3(6) *Copying.* A reasonable number of copies of an open record may be made in the board office.

14.3(7) *Fees.*

a. Copying and postage costs. Price schedules for published materials and for photocopies of records supplied by the board shall be prominently posted in the board office. Copies of records may be made by or for members of the public on board photocopy machines or from electronic storage systems at cost as determined by the custodian and posted in the board office. When the mailing of copies of records is requested, the costs of such mailing may also be charged to the requester.

b. Supervisory and retrieval fees. An hourly fee may be charged for board expenses in supervising the examination of and for the copying of requested records, or for the search and retrieval of such records, when the time required exceeds 15 minutes. The custodian shall prominently post in the board office the hourly fees to be assessed. Hourly fees shall not be in excess of the compensation rate of a board employee who ordinarily would be appropriate and suitable to perform the function.

c. Advance payments. The custodian may require payment of assessed or estimated fees before the custodian processes a request.

657—14.4(22,124,155A) Access to confidential records. Under Iowa Code section 22.7 or other applicable provisions of law, the lawful custodian may disclose certain confidential records to one or more members of the public. Other provisions of law authorize or require the custodian to release specified confidential records under certain circumstances or to particular persons. In requesting the custodian to permit the examination and copying of such a confidential record, the following procedures apply and are in addition to those specified for requests for access to records in rule 14.3(22,124,155A).

14.4(1) *Proof of identity.* A person requesting access to a confidential record shall be required to provide proof of identity or authority to secure access to the record.

14.4(2) *Requests.* The custodian shall require that a request to examine and copy a confidential record be in writing. A person requesting access to such a record shall be required to sign a certified statement or affidavit enumerating the specific reasons justifying access to the confidential record and to provide any proof necessary to establish relevant facts.

14.4(3) *Notice to subject of record and opportunity to obtain injunction.* If the custodian receives a request for access to a confidential record, the custodian may make reasonable efforts to notify any person who is the subject of the record, who is identified in the record, or whose address or telephone number is contained in the record about the request. If it is practicable and in the public interest to delay releasing the information, the custodian may, before releasing the record, give the notified persons an opportunity to seek a court order under Iowa Code section 22.8 or other applicable provision of law prohibiting the custodian from releasing the confidential information. If the custodian gives a notified person this opportunity, the custodian shall give the notified person a specific deadline to obtain a court order prohibiting release of the confidential information and shall not release the confidential information during that time. If the deadline passes and the notified person has not obtained a court order prohibiting

the custodian from releasing the confidential information, the custodian shall release the information to the requester.

14.4(4) *Request denied.* When the custodian denies a request for access to a confidential record, the custodian shall promptly notify the requester. If the requester indicates to the custodian that a written notification of the denial is desired, the custodian shall promptly provide such a notification. Written notification shall be signed by the custodian and shall include:

a. The name and title of the custodian responsible for the denial;

b. A citation to the provision of law vesting authority in the custodian to deny disclosure of the record; and

c. A brief statement of the reasons the requester is being denied access to the record.

14.4(5) *Request granted.* When the custodian grants a request for access to a confidential record to a particular person, the custodian shall notify that person and indicate any lawful restrictions imposed by the custodian on that person's examination and copying of the record.

657—14.5(22,124,155A) Requests for treatment of a record as a confidential record and its withholding from examination. The custodian may treat a record as a confidential record and withhold it from examination only to the extent that the custodian is authorized, by Iowa Code section 22.7, another applicable provision of law, or a court order, to refuse to disclose that record to members of the public.

14.5(1) *Persons who may request.* Any person who would be aggrieved or adversely affected by disclosure of a record, and who identifies a provision of law or court order that authorizes the treatment of the record as a confidential record, may request that the custodian treat the record as such and withhold it from public inspection.

14.5(2) *Request.* A request that a record be treated as a confidential record shall be in writing and shall be filed with the custodian. The request shall set forth the legal and factual basis justifying such confidential record treatment for that record, and the name, address, and telephone number of the person authorized to respond to any inquiry or action of the custodian concerning the request. A person requesting treatment of a record as a confidential record shall also be required to sign a certified statement or affidavit enumerating the specific reasons justifying the treatment of that record as a confidential record and to provide any proof necessary to establish relevant facts. Requests for treatment of a record as a confidential record for a limited time period shall also specify the precise period of time for which that treatment is requested.

A person filing a request for treatment of a record or a portion of a record as a confidential record shall, if possible, accompany the request with a copy of that record from which those portions for which confidential record treatment is being requested have been deleted. If the original record is being submitted to the board by the person requesting confidential treatment at the time the request is filed, the person shall conspicuously indicate on the original record that all or portions of the record are confidential.

14.5(3) *Failure to request.* Failure of a person to request confidential record treatment for a record does not preclude the custodian from treating it as a confidential record. However, if a person who submits business information to the board does not request that it be withheld from public inspection under Iowa Code section 22.7(3) or 22.7(6), the custodian may assume that the person has no objection to disclosure of the record to members of the public.

14.5(4) *Timing of decision.* A decision by the custodian with respect to disclosure of a record to members of the public may be made when a request for its treatment as a confidential record is filed or upon receipt of a request for access to the record by a member of the public.

14.5(5) *Request granted or deferred.* If a request for confidential record treatment is granted or if action on a request is deferred, a copy of the record from which the matter in question has been deleted and a copy of the decision to grant or defer action on the request will be made available for public inspection in lieu of the original record. If the custodian subsequently receives a request for access to the original record, the custodian will make reasonable and timely efforts to notify any person who has filed a request for its treatment as a confidential record of the pendency of that subsequent request.

14.5(6) *Request denied and opportunity to seek injunction.* If the custodian denies a request to treat a record as confidential and to withhold it from public inspection, the custodian shall notify the requester in writing of the denial and the reasons for the denial. If the requester asks, the custodian may delay allowing examination of the record if the delay is reasonable and in good faith, to permit the requester to seek a court order under the provisions of Iowa Code section 22.8 or other applicable provision of law prohibiting public inspection of the record. The custodian shall notify the requester in writing of the deadline for obtaining such a court order. The custodian may continue to delay allowing public inspection only if no request for examination of the record has been received, if the court directs the custodian not to allow public inspection of the record, or to the extent permitted by another applicable provision of law and with the consent of the party requesting access. However, the custodian shall not withhold the record from public inspection for any period of time if the custodian determines the requester has no reasonable grounds to justify treatment of the record as confidential.

657—14.6(22,124,155A) Procedure by which additions, dissents, or objections may be entered into certain records. Except as otherwise provided by law, a person may file a request with the custodian to review, and to have a written statement of additions, dissents, or objections entered into, a record containing personally identifiable information pertaining to that person. This does not authorize a person who is a subject of such a record to alter the original copy of that record or to expand the official record of any board proceeding. A requester shall send the request to review such a record or the written statement of additions, dissents, or objections to Executive Secretary/Director, Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. A request to review such a record or the written statement of additions, dissents, or objections to the record shall be dated and signed by the requester and shall include the current address and telephone number of the requester or the requester's representative.

657—14.7(22,124,155A) Consent to disclosure by the subject of a confidential record. To the extent permitted by any applicable provision of law, a person who is the subject of a confidential record may have a copy of the portion of that record concerning the subject disclosed to a third party. A request for such a disclosure shall be in writing and shall identify the particular record or records that may be disclosed, the particular person or class of persons to whom the record may be disclosed, and any applicable time period during which the record may be disclosed. The person who is the subject of the record and, where applicable, the person to whom the record is to be disclosed shall be required to provide proof of identity. Appearance of counsel before the board on behalf of a person who is the subject of a confidential record is deemed to constitute consent for the board to disclose records about that person to the person's attorney. This rule does not authorize the subject of a record that is confidential under Iowa Code section 272C.6(4) to consent to the release of the record.

657—14.8(22,124,155A) Notice to suppliers of information. When the board requests that a person supply information about that person, the board shall notify the person of the use that will be made of the information, which persons outside the board may routinely be provided this information, which parts of the requested information are required and which are optional, and the consequences of failure to provide the requested information. This notice may be given in these rules, on the written form used to collect the information, on a separate fact sheet or letter, in brochures, in formal agreements, in contracts, in handbooks, in manuals, verbally, or by other appropriate means.

657—14.9(22,124,155A) Disclosures without the consent of the subject.

14.9(1) Open records are routinely disclosed without the consent of the subject.

14.9(2) To the extent allowed by law, disclosure of confidential records may occur without the consent of the subject. Following are instances when disclosure, if lawful, will generally occur without notice to the subject:

a. For a routine use as defined in rule 14.10(22,124, 155A) or in the notice for a particular record system.

b. To a recipient who has provided the board with advance written assurance that the record will be used solely as a statistical research or reporting record, provided that the record is transferred in a form that does not identify the subject.

c. To another government agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law. An authorized representative of the government agency or instrumentality shall have submitted a written request to the board specifying the record desired and the law enforcement activity for which the record is sought.

d. To an individual pursuant to a showing of compelling circumstances affecting the health or safety of any individual, provided a notice of the disclosure is transmitted to the last-known address of the subject.

e. To the legislative services agency as provided in Iowa Code section 2A.3.

f. In the course of employee disciplinary proceedings.

g. In response to a court order or subpoena.

657—14.10(22,124,155A) Routine use. "Routine use" means the disclosure of a record without the consent of the subject or subjects, for a purpose that is compatible with the purpose for which the record was collected, and includes disclosures required to be made by statute other than the public records law, Iowa Code chapter 22.

To the extent allowed by law, the following uses are considered routine uses of all board records:

1. Disclosure to those officers, employees, investigators, members, and agents of the board who have a need for the record in the performance of their duties. The custodian of the record may, upon request of any officer, employee, investigator, member, or agent of the board or on the custodian's own initiative, determine what constitutes legitimate need to use confidential records.

2. Disclosure of information that indicates an apparent violation of law to appropriate law enforcement authorities for investigation and possible criminal prosecution, civil court action, or regulatory order.

3. Disclosure to the attorney general's office for use in performing its official function.

4. Transfers of information among board staff and members; to other state agencies, boards, and departments; to federal agencies; to agencies in other states; to the National Association of Boards of Pharmacy; or to local units of government as appropriate to carry out the board's statutory authority.

5. Information released to the staff of federal or state entities for audit purposes or for purposes of determining whether the board is lawfully operating a program.

6. Any disclosure specifically authorized by the statute under which the record was collected or maintained.

657—14.11(22,124,155A) Consensual disclosure of confidential records.

14.11(1) *Consent to disclosure by a subject individual.* To the extent permitted by law, the subject may consent in writing to board disclosure of confidential records as provided in rule 14.7(22,124,155A).

14.11(2) *Complaints to public officials.* A letter from a subject of a confidential record to a public official that seeks the official's intervention on behalf of the subject in a matter involving the board may, to the extent permitted by law, be treated as an authorization to release to the official sufficient information about the subject to resolve the matter.

657—14.12(22,124,155A) Release to subject.

14.12(1) The subject of a confidential record may file a written request to review confidential records about that person as provided in rule 14.6(22,124,155A). However, the board need not release the following records to the subject:

a. The identity of a person providing information to the board need not be disclosed directly or indirectly to the subject of the information when the information is authorized to be held confidential pursuant to Iowa Code section 22.7(18) or other provision of law.

b. Records need not be disclosed to the subject when they are the work product of an attorney or are otherwise privileged.

c. Peace officers' investigative reports may be withheld from the subject, except as required by the Iowa Code. See Iowa Code section 22.7(5).

d. All information in licensee complaint and investigation files maintained by the board for the purposes of licensee discipline are required to be withheld from the subject prior to the filing of formal charges and the notice of hearing in a licensee disciplinary action.

e. As otherwise authorized by law.

14.12(2) When a record has multiple subjects with interest in the confidentiality of the record, the board may take reasonable steps to protect confidential information relating to another subject.

657—14.13(22,124,155A) Availability of records.

14.13(1) *Open records.* Board records are open for public inspection and copying unless otherwise provided by rule or law.

14.13(2) *Confidential records.* The following records may be withheld from public inspection. Records are listed by category, according to the legal basis for withholding them from public inspection.

a. Tax records made available to the board (Iowa Code sections 422.20 and 422.72);

b. All information in complaint and investigation files maintained by the board for purposes of licensee discipline, except that the information may be released to the licensee once a licensee disciplinary proceeding has been initiated by the filing of formal charges and a notice of hearing (Iowa Code section 272C.6(4));

c. Records of controlled substances disposed of or destroyed (Iowa Code section 124.506);

d. Criminal history or prior misconduct of an applicant for licensure (Iowa Code section 147.21(1));

e. Information relating to the contents of an examination for licensure (Iowa Code section 147.21(2));

f. Information relating to the results of an examination for licensure, other than final score, except that information about the results of an examination may be provided to the person who took the examination (Iowa Code section 147.21(3));

g. Information contained in investigative reports relating to the abuse of controlled substances (Iowa Code section 124.504);

h. Minutes of closed meetings of the board (Iowa Code section 21.5(4));

i. Records of closed-session board disciplinary hearings (Iowa Code sections 272C.6(1) and 21.5(4));

j. Information or records received from a restricted source and any other information or records made confidential by law;

k. Identifying details in final orders, decisions, and opinions to the extent required to prevent a clearly unwarranted invasion of personal privacy or trade secrets under Iowa Code section 17A.3(1)*"d"*;

l. Those portions of board staff manuals, instructions, or other statements issued by the board that set forth criteria or guidelines to be used by board staff in conducting audits, making inspections, negotiating settlements, or selecting or handling cases. This includes operational tactics or allowable tolerances or criteria for the defense, prosecution, or settlement of cases, when disclosure of these statements would:

(1) Enable law violators to avoid detection;

(2) Facilitate disregard of requirements imposed by law; or

(3) Give a clearly improper advantage to persons who are in an adverse position to the board (Iowa Code sections 17A.2 and 17A.3);

m. Personal information in personnel files including, but not limited to, evaluations, discipline, social security number, home address, gender, birth date, and medical and psychological evaluations;

n. Any other records made confidential by law.

14.13(3) *Authority to release confidential records.* The board may in its discretion disclose some confidential records that the board is authorized to refuse to disclose under Iowa Code section 22.7 or

other discretionary provision of law. Any person may request permission to inspect such records. If the board determines that it will release such records, the board may, where appropriate, notify interested parties before releasing the records and withhold the records from inspection as provided in subrule 14.4(3).

657—14.14(22,124,155A) Personally identifiable information. This rule describes the nature and extent of personally identifiable information which is collected, maintained, and retrieved by the board by personal identifier in record systems as defined in rule 14.1(22,124,155A). For each record system, this rule describes the legal authority for the collection of that information and the means of storage of that information. Indication that information in a record system is stored in or on more than one media format should not be interpreted to mean that all information is stored in all such formats. Some information comprising a record may be maintained in or on one type of media while other related information is maintained in or on another. The description also indicates whether the record system contains any confidential information, and includes the legal authority for confidentiality. The record systems maintained by the board are:

14.14(1) *Records of board disciplinary hearings.* These records contain information about licensees, permit holders, and registrants who are the subject of a board disciplinary proceeding or other action. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 17A, 124, 155A, and 272C and is stored electronically, in computer, and on paper. The information contained in "closed session" board hearing records is confidential in whole or in part pursuant to Iowa Code sections 21.5(4) and 272C.6(1).

14.14(2) *Complaint reports.* Complaint and investigative files maintained by the board for purposes of licensee discipline contain information about licensees, permit holders, registrants, and the persons that they serve. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 124 and 155A and is stored electronically, in computer, and on paper. The information contained in these records is confidential in whole or in part pursuant to Iowa Code sections 22.7(18) and 272C.6(4).

14.14(3) *Continuing pharmaceutical education records.* These records contain educational information about pharmacists licensed by the board. This information is collected pursuant to the authority granted in Iowa Code chapter 272C and is stored on paper only.

14.14(4) *Controlled drug samples records.* These records contain information about controlled substance registrants who receive samples of controlled drugs from drug manufacturers. The records include the name, strength, and quantity of controlled drugs received by the registrant, and the identity of the manufacturer or distributor. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 124 and is stored on paper.

14.14(5) *Controlled substance registration records.* These records contain information about pharmacies; individual practitioners including doctors of medicine and surgery, osteopathic medicine and surgery, dentistry, veterinary medicine, podiatry, and optometry; physician assistants; advanced registered nurse practitioners; drug manufacturers, distributors, importers, and exporters; researchers; hospitals and clinics; other health care facilities such as long-term care and nursing care facilities; analytical laboratories; and teaching institutions. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 124 and is stored on paper and in computer.

14.14(6) *Controlled drug destruction reports.* These records contain information about the disposal or destruction of controlled substances in the possession of registrants. The records include the name, strength, quantity, and form of all controlled substances disposed of or destroyed, and the identity of the registrant. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 124 and is stored in computer and on paper. The information contained in these records is confidential pursuant to Iowa Code section 124.506.

14.14(7) *Examination records.* These records contain information about applicants for any of the following examinations: National Association of Boards of Pharmacy Licensure Examination, North American Pharmacist Licensure Examination, Multistate Pharmacy Jurisprudence Examination, Federal Drug Law Examination, and Iowa Drug Law Examination. These records may also contain information

about applicants licensed or pursuing licensure by reciprocity, score transfer, or other means. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 147 and 155A and is stored on paper, electronically, and in computer. The information contained in these records is confidential in part pursuant to Iowa Code sections 147.21, 22.7(1), and 22.7(19).

14.14(8) *Pharmacist-intern records.* These records contain information about pharmacist-interns and their preceptors. This information is collected by the board pursuant to the authority granted in Iowa Code section 155A.6 and is stored on paper, electronically, and in computer. The information contained in these records may be confidential in part pursuant to Iowa Code section 22.7(1).

14.14(9) *Investigative reports.* These records contain information about the subjects of board investigations and the activities of board investigators. The records include a variety of attachments such as interviews, drug audits, medical records, pharmacy records, exhibits, police reports, incident reports, and investigators' observations. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 124, 126, 147, and 155A and is stored electronically, in computer, and on paper. The information contained in these records is confidential pursuant to Iowa Code sections 22.7(2), 22.7(5), 22.7(6), 22.7(9), and 22.7(19); 147.21(1); 124.504; and 272C.6(4).

14.14(10) *Licensure records.* These records contain information about pharmacists, pharmacies, and wholesalers that are licensed by the board. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 126, 147, and 155A and is stored electronically, on paper, in computer, and in the state archives.

14.14(11) *Personnel records.* These records contain personal information about board members and staff. This information is stored on paper and microfiche. The personal information contained in these records may be confidential in whole or in part pursuant to Iowa Code section 22.7(11).

14.14(12) *Nonlicensee investigation files.* These records contain information about nonlicensees, nonregistrants, or non-permit holders. This information is a public record except to the extent that certain information may be exempt from disclosure under Iowa Code section 22.7 or other provision of law.

14.14(13) *Routine inspection reports.* These records contain information about pharmacies, controlled substance registrant offices, manufacturers and distributors, and wholesalers that are inspected by agents of the board to determine compliance with state and federal law. This information is collected by the board pursuant to the authority granted in Iowa Code chapters 124 and 155A and is stored on paper, in computer, and electronically.

14.14(14) *Notifications to the board.* These records contain reports of theft or loss of controlled substances; of pharmacy or drug wholesaler openings, closings, and changes of ownership, location, or responsible person; of the sale or transfer of prescription drugs including controlled substances; of disasters, accidents, or emergencies affecting drugs; and of pharmacists', pharmacist-interns', and pharmacy technicians' names, addresses, or employment changes. This information is collected by the board pursuant to the authority granted in Iowa Code sections 155A.6 and 155A.19 and is stored on paper, electronically, and in computer.

14.14(15) *Precursor substances permit and distribution records.* These records contain information about precursor substances handlers, both vendors and recipients, and information about the distribution, disposal, or destruction of precursor substances. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 124B and is stored in computer and on paper.

14.14(16) *Pharmacy technician records.* These records contain information about pharmacy technicians who are registered by the board. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 155A and is stored on paper and in computer.

657—14.15(22,124,155A) Other groups of records. This rule describes groups of records maintained by the board other than record systems as defined in rule 14.1(22,124,155A). These records are routinely available to the public and may be accessible via the Internet. The board's files of these records do not contain confidential information except where indicated. These records may contain information about individuals and include:

14.15(1) *Board calendars, agenda, news releases, statistical reports and compilations, newsletters, publications, correspondence, and other information intended for the public.* These records may contain

information about individuals, including board members and staff, and are stored on paper, electronically, and in computer.

14.15(2) *Minutes of open meetings of the board.* These records contain information about people who participate in board meetings. This information is collected pursuant to Iowa Code section 21.3 and is stored electronically, in computer, and on paper, and may be accessed via the Internet.

14.15(3) *Records of board rule-making proceedings.* These records may contain information about individuals making written or oral comments on rules proposed by the board. This information is collected pursuant to Iowa Code section 17A.4 and is stored electronically, in computer, and on paper. Information may be accessible via the Internet.

14.15(4) *Board decisions, findings of fact, final orders, advisory opinions, declaratory orders, and other statements of law or policy issued by the board in the performance of its function.* These records are open to the public pursuant to Iowa Code section 272C.6(4), except for information that is confidential, and are stored on paper, electronically, and in computer.

657—14.16(22,124,155A) Computer. The board uses an in-house network of file and print servers and personal computers. This network system permits the comparison of personally identifiable information in one computerized record system with personally identifiable information in another computerized record system.

These rules are intended to implement Iowa Code section 22.11.

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CHAPTER 15
CORRECTIONAL FACILITY PHARMACY PRACTICE

657—15.1(155A) Purpose and scope. It is the intent of these rules to authorize the department of corrections to distribute prescription drugs to inmates in correctional institutions by and through a network of pharmacies located in facilities operated pursuant to Iowa Code chapter 246. The pharmacies shall be licensed by the board with limited-use pharmacy licenses designated as correctional facility pharmacy licenses and shall be located in facilities operated pursuant to Iowa Code chapter 246. Pharmacists shall be responsible for any delegated act performed by supportive personnel under their supervision. The requirements of these rules for correctional facility pharmacy practice are in addition to the requirements of 657—Chapter 8 and other rules of the board relating to the services provided by the pharmacies.

657—15.2(126,155A) Definitions. For purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy examiners.

"Department" means the Iowa department of corrections.

"Medication prescription order" means an order for a drug or device for a person in custody status in a correctional institution, originated by a practitioner authorized to prescribe, and which meets the information requirements for a prescription order but is recorded, distributed, and administered as though it were a medication order.

"Provisional stock" means a limited inventory of drugs stored outside the confines of the correctional facility pharmacy and accessible to designated health services staff for the purpose of initiating emergency or first-dose medication prescription orders issued during periods when the pharmacist is unavailable.

657—15.3(155A) Pharmacist in charge. One professionally competent, legally qualified pharmacist in charge in each pharmacy shall be responsible for, at a minimum, the following:

1. Ensuring that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services;
2. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy;
3. Ensuring that a quarterly inspection of all pharmaceuticals located at the correctional facility including emergency and provisional stocks located outside the confines of the pharmacy is completed and documented;
4. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy;
5. Preparing a written operations manual governing pharmacy functions; periodically reviewing and revising those policies and procedures to reflect changes in processes, organization, and other pharmacy functions; ensuring that policies and procedures are consistent with board rules and the policies and rules of the department relating to pharmaceutical services; and ensuring that all pharmacy personnel are familiar with the contents of the manual;
6. Ensuring that a pharmacist performs prospective drug use reviews as specified in rule 657—8.21(155A);
7. Ensuring that a pharmacist provides drug information to other health professionals, to other caregivers, and to patients as required or requested;
8. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel;
9. Delivering drugs to the patient or the patient's agent;
10. Ensuring that patient medication records are maintained as specified in rule 15.8(124,126,155A);
11. Training pharmacy technicians and supportive personnel;

12. Establishing policies for the procurement and storage of prescription drugs and devices and other products dispensed from the pharmacy;

13. Disposing of and distributing drugs from the pharmacy;

14. Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all drugs as required by applicable state and federal laws, rules, and regulations;

15. Establishing and maintaining effective controls against the theft or diversion of prescription drugs and records for such drugs;

16. Ensuring the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.

657—15.4(155A) Reference library. References may be printed or computer-accessed. Each correctional facility pharmacy shall have on site, as a minimum, one current reference from each of the following categories, including access to current periodic updates.

1. The Iowa Pharmacy Law and Information Manual.
2. A patient information reference that includes or provides patient information in compliance with rule 657—6.14(155A).
3. A reference on drug interactions.
4. A general information reference.
5. A drug equivalency reference.
6. A reference on natural or herbal medicines.
7. The readily accessible telephone number of a poison control center that serves the area.
8. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—15.5(124,155A) Security. The pharmacy shall be located in an area or areas that facilitate the provision of services to patients. The following conditions must be met to ensure appropriate control over drugs and chemicals in the pharmacy:

15.5(1) *Locked areas.* All areas occupied by the correctional facility pharmacy or where drugs or devices are maintained or stored shall be lockable by a key, combination, or electronic device so as to prevent access by unauthorized personnel and shall be locked when unoccupied or unattended.

15.5(2) *Access when pharmacist absent.* The pharmacist in charge, with the concurrence of the department, shall establish and implement policies and procedures for the security of the correctional facility pharmacy. Policies and procedures shall identify who will have access to the pharmacy when the pharmacist is absent from the facility and the procedures to be followed for obtaining drugs and chemicals during that absence.

15.5(3) *Pharmacist responsibility.* Each pharmacist, while on duty, shall be responsible for the security of the prescription department. This responsibility includes provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs or devices, controlled substances, records for such drugs and devices, and patient records as provided in 657—Chapter 21 and rule 657—8.16(124,155A). Policies and procedures shall identify the minimum amount of time that a pharmacist is available at the correctional facility pharmacy.

15.5(4) *Drugs in other areas of facility.* All drugs distributed from the pharmacy to other areas of the correctional facility for subsequent administration to inmates shall be kept in locked storage when not in use, with access restricted to the medication nurse or qualified designee.

657—15.6 and **15.7** Reserved.

657—15.8(124,126,155A) Drug distribution and dispensing controls. Prescription drugs may be distributed or dispensed only from the original or a properly verified medication prescription order. There shall be no transcribing of medication orders by nursing or clerical staffs except for their own records.

15.8(1) *Required information.* Medication prescription orders written in inmate health records shall include the following information:

a. Inmate name, identification number, and location;

b. Drug name, strength, dosage form, and quantity or duration;

c. Directions for use;

d. Date of issue;

e. Prescriber's name or signature and office address if different from that of the correctional facility or if not on file in the correctional facility pharmacy;

f. Prescriber's DEA number for controlled substances if not on file in the correctional facility pharmacy.

15.8(2) *Original maintained.* The original medication prescription order and the medication administration record shall be maintained for a minimum of two years in the inmate's health record.

15.8(3) *Effect upon transfer of inmate.* Current medication prescription orders remain in effect when an inmate is transferred within the correctional institution system.

15.8(4) *Unit dose dispensing.* Drugs dispensed in a unit dose dispensing system for subsequent administration by nurses or other qualified individuals shall be packaged and labeled in compliance with the provisions of rule 657—22.1(155A).

15.8(5) *Drug administration.* Registered nurses may issue an inmate's prepackaged drugs from the supply distributed by the pharmacist for that inmate into envelopes or other appropriate containers to facilitate subsequent administration by qualified individuals. Said qualified individuals shall use the medication administration record, or a properly verified copy thereof, to administer and document administration of those drugs to the inmate. The single unit or unit dose packaging shall remain intact to the point of administration.

15.8(6) *Dispensing for inmate self-administration.* Drugs dispensed for self-administration by an inmate, either during the inmate's incarceration or subsequent to the inmate's departure from department custody status, shall be packaged and labeled in accordance with rule 657—6.10(155A).

15.8(7) *Drug product selection.* Correctional facility pharmacies shall be exempt from the patient notification requirements of Iowa Code section 155A.32 when exercising drug product selection.

15.8(8) *Provisional stock.* Provisional stock of prescription drugs may be supplied for use by authorized personnel pursuant to 657—22.7(124,155A). A record shall be made of all withdrawals from provisional stock. The original or properly verified copy of the emergency medication prescription order shall be left with the withdrawal record. The withdrawal record shall include the following information:

a. Inmate's name and identification number;

b. Prescriber;

c. Name, strength, dosage form, and quantity of the drug withdrawn;

d. Signature, unique identification, or initials of the authorized person making the withdrawal;

e. Date and time of administration;

f. Quantity administered, if different from the quantity withdrawn;

g. Signature, unique identification, or initials of the authorized person administering the drug;

h. Returns to the pharmacy, including quantity returned;

i. Waste, which shall be witnessed and cosigned by another licensed health care professional.

657—15.9 Reserved.

657—15.10(124,126,155A) Policies and procedures. The pharmacist in charge shall develop and implement written policies and procedures for the pharmacy drug distribution system consistent with board rules and department policies and procedures pertaining to pharmaceutical services. Policies and procedures shall address, but not be limited to, the following:

1. Controlled substances;
2. Formulary or drug list;
3. Stop orders;
4. Drug sample use and distribution;

5. Drug recalls;
6. Outdated drugs;
7. Patient records;
8. Inspection of drug inventories;
9. Adverse reaction reports;
10. Furlough or discharge medications;
11. Provisional stocks of drugs;
12. Drugs brought into the facility;
13. Medication administration and records;
14. Drug compounding;
15. Sterile products;
16. Access to the pharmacy in the absence of the pharmacist;
17. Transfers of drugs between facilities.

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 124.308, 126.10, 126.11, 155A.13, 155A.27, 155A.28, 155A.31, 155A.32, and 155A.34 through 155A.36.

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CHAPTER 16
NUCLEAR PHARMACY PRACTICE

[Prior to 12/14/88, see Pharmacy Examiners Board 657—8.8(155A)]

657—16.1(155A) Purpose and scope. It is unlawful to receive, possess or transfer radioactive drugs except in accordance with the provisions of Iowa Code chapter 155A. It is also unlawful for any person to provide radiopharmaceutical services unless the person is a pharmacist or a person acting under the direct supervision of a pharmacist acting in accordance with the provisions of Iowa Code chapter 155A, board rules and rules of the environmental protection commission. It is not unlawful for a medical practitioner to receive, possess, or transfer radioactive drugs for administration to patients as provided in Iowa Code chapter 148. No person may receive, acquire, possess, use, transfer, or dispose of any radioactive material except in accordance with the conditions set forth by the environmental protection commission pursuant to the provisions of Iowa Code chapter 455B. The requirements of these nuclear pharmacy rules are in addition to and not in substitution for 657—Chapter 8 and other applicable provisions of rules of the board and the environmental protection commission or the public health department.

657—16.2(155A) Definitions.

"Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical.

"Board" means the Iowa board of pharmacy examiners.

"Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"Qualified nuclear pharmacist" means a person currently licensed to practice pharmacy in Iowa who meets the qualifications established by rule 16.3(155A).

"Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine the radiopharmaceuticals' suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

"Radiopharmaceutical service" means, but is not limited to, the preparation, dispensing, labeling and delivery of radiopharmaceuticals; the compounding of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, as necessary or required, of the therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a nuclear pharmacy.

657—16.3(155A) General requirements for qualified nuclear pharmacist. A qualified nuclear pharmacist shall meet all requirements of either alternative one or alternative two established in subrules 16.3(1) and 16.3(2), respectively.

16.3(1) *Alternative one.* A qualified nuclear pharmacist shall:

a. Meet minimum standards of training for medical uses of radioactive materials; and

b. Be a currently licensed pharmacist in the state of Iowa; and

c. Submit an affidavit of experience and training to the board; and

d. Have completed one of the following nuclear pharmacy training alternatives:

(1) Received a minimum of 90 contact hours of didactic instruction in nuclear pharmacy from an accredited college of pharmacy. In addition, the pharmacist shall have attained a minimum of 160 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy that provides nuclear pharmacy services or in a structured clinical nuclear pharmacy training program of an accredited college of pharmacy.

(2) Successfully completed a nuclear pharmacy residency accredited by the American Society of Health-System Pharmacists (ASHP).

(3) Successfully completed a certificate program in nuclear pharmacy accredited by the American Council on Pharmaceutical Education (ACPE).

16.3(2) *Alternative two.* A qualified nuclear pharmacist shall:

a. Be a currently licensed pharmacist in the state of Iowa; and

b. Be certified by the Board of Pharmaceutical Specialties as a board-certified nuclear pharmacist (BCNP); and

c. Submit an affidavit of BCNP credentials to the board.

657—16.4(155A) General requirements for pharmacies providing radiopharmaceutical services.

16.4(1) *Qualified nuclear pharmacist.* A license to operate a pharmacy providing radiopharmaceutical services shall be issued only to a qualified nuclear pharmacist who shall be the pharmacist in charge of the pharmacy. The pharmacist in charge shall be responsible for, at a minimum, the requirements in rule 657—6.2(155A). All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct personal supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist is responsible for all operations of the pharmacy and, except in emergency situations, shall be in personal attendance at all times that the pharmacy is open for business.

16.4(2) *Space requirements.* Nuclear pharmacies shall have adequate space, commensurate with the scope of services required and provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradioactive drugs and shall be secured from unauthorized personnel. All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least 25 square feet of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance, and office areas.

16.4(3) *Personnel appropriately trained.* The pharmacist in charge shall be responsible for ensuring that all pharmacy personnel have been appropriately and adequately trained for their assigned tasks.

16.4(4) *Records required.* Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules of the board and the environmental protection commission.

16.4(5) *Compliance with laws.* Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs.

16.4(6) *Prescription and office use.* Radioactive drugs shall be dispensed only upon a prescription order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals to practitioners for office use.

16.4(7) *Outer-container label.* In addition to any of the board's labeling requirements for nonradioactive drugs, the immediate outer container of a radioactive drug to be dispensed shall also be labeled with:

a. The standard radiation symbol;

b. The words "Caution — Radioactive Material";

c. The name of the radionuclide;

d. The chemical form;

e. The amount of radioactive material contained, in millicuries or microcuries;

f. If the radioactive drug is a liquid, the volume in cubic centimeters;

g. The requested calibration time for the amount of radioactivity contained.

16.4(8) *Immediate-container label.* The immediate container shall be labeled with:

a. The standard radiation symbol;

b. The words "Caution — Radioactive Material";

c. The name of the pharmacy; and

d. The prescription number.

16.4(9) *Radioactivity.* The amount of radioactivity for each individual preparation shall be determined by radiometric methods immediately prior to dispensing.

16.4(10) *Redistribution.* A nuclear pharmacy may redistribute to another nuclear pharmacy or authorized party radioactive drugs that are the subject of an approved new drug application if the pharmacy does not process the radioactive drugs in any manner or violate the product packaging.

657—16.5(155A) Library. Each nuclear pharmacy shall have access to the following references. References may be printed or computer-accessed and shall be current editions or revisions.

1. United States Pharmacopoeia/National Formulary, with supplements;
2. The Iowa Pharmacy Law and Information Manual;
3. State rules and federal regulations governing the use of applicable radioactive materials;
4. Additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served.

657—16.6(155A) Minimum equipment requirements. Each nuclear pharmacy shall maintain the following equipment for use in the provision of radiopharmaceutical services:

1. Laminar flow hood;
2. Dose calibrator;
3. Refrigerator;
4. Single-channel scintillation counter;
5. Microscope;
6. Autoclave, or access to one;
7. Incubator, or access to one;
8. Radiation survey meter;
9. Other equipment necessary for the radiopharmaceutical services provided as required by the board.

A pharmacy may request waiver or variance from a provision of this rule pursuant to the procedures and requirements of 657—Chapter 34.

These rules are intended to implement Iowa Code sections 155A.4, 155A.13, 155A.28, and 155A.31.

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CHAPTER 17
WHOLESALE DRUG LICENSES

657—17.1(155A) Definitions.

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Board" means the Iowa board of pharmacy.

"Distribute" means the delivery of a prescription drug or device.

"Drug sample" means a drug that is distributed without monetary consideration to a pharmacist or practitioner. "Drug sample" does not include drugs intended for patients who would otherwise not receive needed drugs due to their inability to pay.

"Manufacturer" means a person or business engaged in the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes packaging or repackaging of the substances or labeling or relabeling of the substances' containers.

"Prescription drug" means any of the following:

1. A substance for which federal or state law requires a prescription before it may be legally dispensed to the public.

2. A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with one of the following statements:

- Caution: Federal law prohibits dispensing without a prescription.
- Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- Rx only.

3. A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

"Proprietary medicine" or *"over-the-counter (OTC) medicine"* means a nonnarcotic drug or device that may be sold without a prescription and that is labeled and packaged in compliance with applicable state or federal law.

"Reverse distribution" means the receipt of prescription drugs including controlled substances, whether received from Iowa locations or shipped to Iowa locations, for the purposes of destroying the drugs or returning the drugs to their original manufacturers or distributors.

"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

1. The sale, purchase, or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons. For purposes of this chapter, "emergency medical reasons" includes transfers of prescription drugs by a pharmacy to another pharmacy to alleviate a temporary shortage;

2. The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

3. The lawful distribution of drug samples by manufacturers' representatives or wholesale salespersons;

4. The sale, purchase or trade of blood and blood components intended for transfusion; or

5. Intracompany sales.

"Wholesale distributor" or *"wholesaler"* means a person or business operating or maintaining, either within or outside this state, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs, medicinal chemicals, medicines, or poisons are sold, manufactured, dispensed, stocked, exposed, or offered for sale at wholesale in this state. "Wholesaler" includes, but is not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; reverse distributors; and pharmacies that conduct wholesale distributions exceeding 5 percent of gross annual sales of prescription drugs. "Wholesaler" does not include those wholesalers who sell

only OTC medicines or manufacturers' representatives lawfully distributing drug samples to authorized practitioners.

"Wholesale salesperson" or *"manufacturer's representative"* means an individual who takes purchase orders on behalf of a wholesaler for prescription drugs, medicinal chemicals, medicines, or poisons. "Manufacturer's representative" also means a person designated by a pharmaceutical manufacturer to lawfully distribute drug samples to authorized practitioners.

657—17.2 Reserved.

657—17.3(155A) Wholesale drug license. Every wholesaler as defined in rule 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 controlled substances shall also register pursuant to 657—Chapter 10.

17.3(1) *Application form.* Application for licensure and license renewal shall be on forms provided by the board. Application for wholesale drug licensure shall require an indication of the type of wholesale operation and the wholesaler 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 wholesaler ownership classification shall be further identified and explained on the application. The name, address, and telephone numbers of at least one contact person for the licensed facility shall be identified. A list of all states in which the wholesaler is licensed and all trade or business names used by the wholesaler shall be included on or with the application. The application shall identify, if the wholesaler is located outside Iowa, applicable home state license information and DEA and FDA license or registration information. The application shall also provide information regarding any past criminal convictions or adverse actions against licenses or registrations held by the licensee or facility managers.

17.3(2) *License expiration and renewal.* A wholesale drug license shall be renewed before January 1 of each year. The fee for a new or renewal license shall be $300.

a. Late payment penalty. Failure to renew the license before January 1 shall require payment of the renewal fee and a penalty fee of $300. Failure to renew the license before February 1 following expiration shall require payment of the renewal fee and a penalty fee of $400. Failure to renew the license before March 1 following expiration shall require payment of the renewal fee and a penalty fee of $500. Failure to renew the license before April 1 following expiration shall require payment of the renewal fee and a penalty fee of $600 and may require an appearance before the board. In no event shall the combined renewal fee and penalty fee for late renewal of a wholesale drug license exceed $900.

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

17.3(3) *Inspection of new wholesale drug distribution facility.* If a new wholesale drug distribution location within Iowa was not a licensed wholesale drug distribution site immediately prior to the proposed opening of the new wholesale facility, the location shall require an on-site inspection by a pharmacy board inspector prior to the issuance of the wholesale drug license. The purpose of the inspection is to determine compliance with requirements pertaining to space, equipment, drug storage safeguards, and security. Inspection may be scheduled anytime following submission of necessary license and registration applications and prior to beginning wholesale drug distribution. Prescription drugs, including controlled substances, may not be delivered to a new wholesale drug distribution facility prior to satisfactory completion of the opening inspection.

17.3(4) *Wholesale drug license changes.*

a. Ownership change. When ownership of a licensed drug wholesaler changes, the licensee shall submit to the board written notification including the name, address, and license number of the wholesaler and the effective date of the change. Notification shall also identify the new ownership classification and the owners, partners, or corporate officers as indicated in subrule 17.3(1). In those cases in which the wholesaler 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 wholesaler continues to exist following the stock sale or transfer. A new license shall not be required for a change of ownership.

b. Name or location change. When a licensed drug wholesaler changes its name or location, a new wholesale drug license application with a license fee as provided in 17.3(2) shall be submitted to the board office. Upon receipt of the fee and properly completed application, the board will issue a new license certificate. The old license certificate shall be returned to the board office within ten days of the change of name or location. A change of wholesaler location within Iowa, if the new location was not a licensed drug wholesaler immediately prior to the relocation, shall require an on-site inspection of the new location as provided in subrule 17.3(3).

17.3(5) *Drug wholesaler closing.* A licensee discontinuing wholesale distribution of prescription drugs in or into Iowa shall submit to the board, with the current wholesale drug license certificate, written notification indicating the effective date of closing or discontinuing business in Iowa. If the drug wholesaler had been engaged in the distribution of controlled substances in Iowa, the written notification shall identify by name, address, and appropriate license numbers the facility or facilities to which controlled substances records and any final inventory of controlled substances have been transferred.

17.3(6) *Failure to complete licensure process.* An application for a wholesale drug 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 wholesaler'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.

657—17.4(155A) Minimum qualifications. The board will consider the following factors in determining eligibility for licensure of persons or businesses that engage in the wholesale distribution of prescription drugs:

1. Any convictions of the applicant under federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
2. Any felony convictions of the applicant under federal, state, or local laws;
3. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
5. Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
6. Compliance with licensing requirements under previously granted licenses, if any;
7. Compliance with the requirements to maintain or make available to the board, its agents or authorized personnel, or to federal, state, or local law enforcement officials those records required to be maintained by wholesalers; and
8. Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

657—17.5(155A) Personnel. Licensed wholesalers shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling,

including a description of their duties and a summary of their qualifications. The wholesaler shall employ personnel with the education or experience appropriate to the responsibilities of the position held by the individual.

657—17.6(155A) Responsibility for conduct. A licensed drug wholesaler shall be held responsible for actions of the wholesaler's managerial agent when the conduct of the agent may fairly be assumed to represent the policy of the wholesaler. "Managerial agent" includes, but is not necessarily limited to, an officer or director of a corporation or an association or a partner of a partnership, and includes a person having management responsibility for submissions to the FDA regarding the development or approval of any drug product; the production, quality assurance, or quality control of any drug product; or research and development of any drug product.

17.6(1) *Misrepresentative deeds.* A managerial agent 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 the manufacture, distribution, or marketing of prescription drugs.

17.6(2) *Unethical conduct or behavior.* A managerial agent shall not exhibit unethical behavior in connection with the manufacture, distribution, or marketing of prescription drugs or refuse to provide reasonable information or answer reasonable questions for the benefit of a health professional or a patient. Unethical behavior shall include, but not be limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.

657—17.7(124,155A) Distribution to authorized licensees. A wholesaler shall be responsible for verifying, prior to the distribution of a prescription drug, the authority of the person or business to whom the distribution is intended. Such verification may include, but is not limited to, obtaining a copy of the license under which the person or business claims authority to possess the prescription drug or contacting the appropriate licensing authority for verification of the licensee's authority to possess the prescription drug.

657—17.8(124,155A) Written policies and procedures. Wholesalers shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall also include in their written policies and procedures the following:

17.8(1) *Oldest stock distributed first.* A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

17.8(2) *Recalls and market withdrawals.* A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

a. Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement agency or other government agency, including the board;

b. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

c. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

17.8(3) *Emergency and disaster plan.* A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

17.8(4) *Outdated drugs.* A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs.

17.8(5) *Exception.* The procedure required by subrule 17.8(1) does not apply to reverse distribution operations. All other procedures addressed in this rule are required of reverse distribution operations.

17.8(6) *Drugs supplied to salesperson/representative.* If supplying drugs to wholesale salespersons or manufacturers' representatives, a procedure directing that the security, storage, and record-keeping requirements contained in these rules shall be maintained by those wholesale salespersons or manufacturers' representatives.

657—17.9(155A) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
2. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
3. Have a quarantine area for storage of outdated, damaged, unsafe, deteriorated, misbranded, or adulterated prescription drugs; for drugs that are in immediate or sealed outer or sealed secondary containers that have been opened; for drugs that have been identified as being defective or are believed to be defective; and for drugs that do not meet the FDA-approved criteria for the product;
4. Be maintained in a clean and orderly condition;
5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

657—17.10(124,155A) Security.

17.10(1) *Secure from unauthorized entry.* All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

a. Access from outside the premises shall be kept to a minimum and be well controlled.

b. The outside perimeter of the premises shall be well lighted.

c. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

17.10(2) *Alarm.* All facilities shall be equipped with an alarm system to deter entry after hours.

17.10(3) *Security system.* All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

657—17.11(155A) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or with requirements in the current edition of an official compendium.

17.11(1) *Controlled room temperature.* If no storage requirements are established for a prescription drug, the drug may be held at "controlled room temperature" to help ensure that its identity, strength, quality, and purity are not adversely affected. "Controlled room temperature" means the room temperature is maintained thermostatically between 15 degrees and 30 degrees Celsius (59 degrees and 86 degrees Fahrenheit).

17.11(2) *Documentation.* Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs.

17.11(3) *Exception.* The storage requirements of this rule do not apply to reverse distribution operations.

657—17.12 Reserved.

657—17.13(155A) Drugs in possession of representatives. If a wholesaler is supplying samples or other forms of prescription drugs to wholesale salespersons or manufacturers' representatives, the wholesaler shall be responsible for ensuring that those representatives maintain distribution records and maintain the drugs under appropriate security and storage conditions pursuant to the requirements of these rules.

657—17.14(155A) Examination of materials.

17.14(1) *Receipt shipment.* Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

17.14(2) *Outgoing shipment.* Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

17.14(3) *Type of inspection.* Examination or inspection shall be completed in a manner to ensure the stated intent of this rule. Inspection may be completed by use of electronic surveillance or personal examination.

657—17.15(155A) Returned, damaged, and outdated prescription drugs.

17.15(1) *Quarantine required.* Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.

17.15(2) *Seal opened.* Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

17.15(3) *Drug safety, purity uncertain.* Unless examination, testing, or other investigation proves that a drug meets appropriate standards of safety, identity, strength, quality, and purity, a prescription drug that has been returned under conditions that cast doubt on the drug's safety, identity, strength, quality, or purity shall be destroyed or returned to the supplier. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesaler shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling as a result of storage or shipping.

17.15(4) *Exception.* The requirements of this rule do not apply to reverse distribution operations.

657—17.16(124,155A) Record keeping. Wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs, including outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

17.16(1) *Transaction records.* Transaction records shall include the following information:

a. The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

b. The identity and quantity of the drugs received and distributed or disposed of;

c. The dates of receipt and distribution or other disposition of the drugs; and

d. If a distribution transaction, the recipient of the drugs, including the name and principal address of the purchaser or transferee and the address to which the drugs were shipped.

17.16(2) *Records maintained.* Inventories and records shall be made available for inspection and photocopying by any authorized official of the board or of any governmental agency charged with enforcement of these rules for a period of two years following disposition of the drugs. A biennial inventory of controlled substances shall be maintained for a minimum of four years from the date of the inventory.

17.16(3) *Inspection of records.* Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be available for inspection within two working days of a request by an authorized official of the board or of any governmental agency charged with enforcement of these rules.

17.16(4) *Confidentiality of patient information.* A wholesaler shall obtain and maintain patient-specific data only as necessary for the health and safety of the patient. Any patient-specific

information in the possession of a wholesaler shall be maintained in compliance with the patient confidentiality and security requirements of rules 657—8.16(124,155A) and 657—21.2(124,155A).

657—17.17(124,155A) Compliance with federal, state, and local laws. Wholesalers shall operate in compliance with applicable federal, state, and local laws, rules, and regulations.

17.17(1) *Access by authorized officials.* Wholesalers shall permit the board and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to wholesalers' premises and delivery vehicles.

17.17(2) *Controlled substance registrations.* Wholesalers that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA) and shall comply with all applicable federal, state, and local laws, rules, and regulations.

657—17.18(155A) Discipline. Pursuant to 657—Chapters 35 and 36, the board may deny, suspend, or revoke a wholesale drug license for any violation of Iowa Code chapter 124, 124A, 124B, 126, 155A, or 205 or a rule of the board promulgated thereunder.

These rules are intended to implement Iowa Code sections 124.301 through 124.303, 124.306, 155A.4, and 155A.17.

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CHAPTER 18
CENTRALIZED PRESCRIPTION FILLING AND PROCESSING

657—18.1(155A) Purpose and scope. The purpose of this chapter is to provide standards for centralized prescription drug order filling or centralized prescription processing by a pharmacy. Any facility established for the purpose of filling or processing prescription drug orders on behalf of other pharmacies shall be licensed as a pharmacy and shall hold all necessary registrations. A hospital pharmacy may participate in centralized prescription filling only of prescription drug orders for noncontrolled substances pursuant to these rules. A hospital pharmacy may engage in centralized prescription processing pursuant to the requirements of rule 657—7.7(155A). Except as specifically identified in the rules, the requirements of these rules for centralized prescription filling or centralized prescription processing are in addition to the requirements of 657—Chapters 6, 7, and 8, and other rules of the board relating to services provided by pharmacies.

657—18.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Central fill pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription drug order filling on behalf of the originating pharmacy pursuant to these rules.

"Centralized prescription drug order filling" or *"centralized filling"* means the filling of a prescription drug order by a pharmacy on behalf of another pharmacy. "Centralized filling" does not include the processing or dispensing of a prescription drug order but may include any of the following filling functions:

1. Receiving prescription drug orders from the originating pharmacy;
2. Interpreting or clarifying prescription drug orders;
3. Entering prescription drug order information into a pharmacy's prescription record system;
4. Selecting, counting, and placing the prescribed drug into an appropriate prescription container;
5. Affixing the prescription label, including any auxiliary labels, to the prescription container;
6. Obtaining refill and substitution authorizations;
7. Verifying all filling processes performed by the central fill pharmacy.

"Centralized prescription drug order processing" or *"centralized processing"* means the processing of a prescription drug order by a pharmacy on behalf of another pharmacy. "Centralized processing" does not include the filling or dispensing of a prescription drug order but may include any of the following processing functions:

1. Interpreting or clarifying prescription drug orders;
2. Entering prescription drug order information into a pharmacy's prescription record system;
3. Interpreting clinical data for prior authorization for dispensing;
4. Performing formulary-directed therapeutic interchange.

"Central processing pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription drug order processing on behalf of the originating pharmacy pursuant to these rules.

"DEA" means the U.S. Department of Justice, Drug Enforcement Administration.

"Dispense" means the delivery of a prescription drug or device to an ultimate user or the ultimate user's agent by or pursuant to the lawful order of a practitioner. "Dispense" includes:

1. Receiving the prescription drug order from the patient, the patient's agent, or the prescriber;
2. Delivering the filled prescription to the patient or the patient's agent;
3. Providing drug information concerning a patient's drug therapy;
4. Providing patient counseling;
5. Providing medication therapy management.

"Hospital" means a facility licensed pursuant to Iowa Code chapter 135B.

"Hospital pharmacy" means and includes a pharmacy licensed by the board and located within any hospital, health system, institution, or establishment which maintains and operates organized facilities

for the diagnosis, care, and treatment of human illnesses to which persons may or may not be admitted for overnight stay at the facility.

"Mail order pharmacy" means a pharmacy located within a United States jurisdiction whose primary business is to dispense a prescription drug or device pursuant to a valid prescription drug order and to deliver the drug or device to a patient, including a patient in this state, via the United States Postal Service, a common carrier, or a delivery service. "Mail order pharmacy" includes a pharmacy that does business via the Internet or other electronic media.

"Medication therapy management" means the review of drug therapy regimens of a patient by a pharmacist for the purpose of evaluating and rendering advice to a practitioner, or for the purpose of evaluating and modifying the drug regimen in accordance with a collaborative drug therapy management protocol pursuant to rule 657—8.34(155A).

"Originating pharmacy" means a pharmacy that receives a prescription drug order from a patient, the patient's agent, or a prescriber, outsources prescription filling or processing functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent.

657—18.3(155A) General requirements.

18.3(1) *Essential qualifications.* An originating pharmacy may outsource prescription drug filling to a central fill pharmacy or prescription drug order processing to a central processing pharmacy provided the pharmacies:

a. Have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and

b. Share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to perform the contracted functions.

18.3(2) *Legal compliance.* An originating pharmacy, a central fill pharmacy, and a central processing pharmacy shall comply with all provisions applicable to the pharmacy contained in federal and state laws, rules, and regulations to the extent applicable for the specific filling or processing activity and these rules, including but not limited to the following:

a. Each pharmacy located within Iowa shall maintain Iowa pharmacy licensure and, if the pharmacy dispenses controlled substances, the pharmacy shall maintain DEA and Iowa controlled substances registrations.

b. Each pharmacy located outside Iowa shall maintain Iowa nonresident pharmacy licensure in addition to the licensure requirements of the pharmacy's home state.

c. Each pharmacist providing centralized prescription drug order processing or filling functions as an employee or agent of a central processing or central fill pharmacy located within Iowa shall maintain active licensure to practice pharmacy in Iowa.

d. Pharmacies shall comply with Iowa board rules relating to the duties that must be performed by a pharmacist.

e. Pharmacies shall comply with Iowa requirements for supervision of pharmacy technicians.

18.3(3) *Originating pharmacy responsibility.* Except as specifically provided by this subrule, the originating pharmacy shall be responsible for all dispensing functions as the term "dispense" is defined in rule 18.2(155A). An originating pharmacy contracting only for centralized filling shall retain responsibility for all processing functions, and an originating pharmacy contracting only for centralized processing shall retain responsibility for all filling functions.

a. A mail order pharmacy engaged in the centralized filling of prescription drug orders may deliver a filled prescription directly to the patient and shall not be required to return the filled prescription to the originating pharmacy.

b. A central fill or a central processing pharmacy that shares a common central processing unit with the originating pharmacy may perform prospective drug use review (DUR) pursuant to rule 657—8.21(155A). Only a pharmacist shall perform the DUR; the review shall not be delegated to a pharmacy technician, registered nurse, or other pharmacy support person. The pharmacist performing the DUR shall document in the shared patient record all concerns, recommendations, observations, and

comments resulting from that review. The pharmacist at the originating pharmacy shall utilize the DUR notes in counseling the patient pursuant to rule 657—6.14(155A).

18.3(4) *Central fill label requirements.* The label affixed to the prescription container filled by a central fill pharmacy on behalf of an originating pharmacy shall include the following:

a. A unique identifier indicating that the prescription was filled at the central fill pharmacy;

b. Serial number (a unique identification number of the prescription) as assigned by the originating pharmacy;

c. The name, address, and telephone number of the originating pharmacy;

d. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

e. The name of the prescribing practitioner;

f. The date the prescription is filled by the central fill pharmacy;

g. The directions or instructions for use, including precautions to be observed;

h. Unless otherwise directed by the prescriber, the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)".

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)";

i. The initials or other unique identification of the pharmacist in the originating pharmacy who performed drug use review and transmitted the prescription drug order to the central fill pharmacy.

657—18.4 Reserved.

657—18.5(155A) Patient notification and authorization.

18.5(1) *Prior notification and authorization.* A pharmacy that outsources prescription drug order filling or prescription drug order processing to another pharmacy shall, prior to outsourcing a patient's prescription:

a. Notify the patient or the patient's agent that prescription filling or processing may be outsourced to another pharmacy.

b. Provide the name of the pharmacy that will be filling or processing the prescription or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may fill or process the prescription, the patient shall be notified of this fact. Notification shall be provided through a notice to the patient or the patient's agent by means of a sign prominently displayed in the originating pharmacy and through written notice provided to the patient or the patient's agent prior to implementation of the program or upon commencement of services to a new patient, as applicable.

c. If a patient provides the originating pharmacy with notification that the patient no longer authorizes the originating pharmacy to outsource the patient's prescription drug orders, the originating pharmacy shall discontinue outsourcing the filling or processing of the patient's prescription drug orders.

18.5(2) *Exception.* The provisions of this rule do not apply to a patient in a facility, such as a hospital or long-term care facility, where Iowa law requires that drugs be administered to the patient by a health care professional.

657—18.6 to **18.9** Reserved.

657—18.10(155A) Policy and procedures.

18.10(1) *Manual maintained.* A policy and procedure manual relating to centralized filling or centralized processing activities shall be maintained at all pharmacies involved in centralized filling or centralized processing and shall be available for inspection and copying by the board or an agent of the board.

18.10(2) *Manual contents.* The manual shall:

a. Outline the responsibilities of each of the pharmacies;

b. Include a list of the names, addresses, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized filling or centralized processing;

c. Include evidence that all licenses and registrations have been verified to be current and in good standing, identifying the individual verifying license and registration status and the method used to verify status; and

d. Include, but not necessarily be limited to, policies and procedures for:

(1) Protecting the confidentiality and integrity of patient information;

(2) Protecting each patient's freedom of choice of pharmacy services;

(3) Maintaining appropriate records to identify the name, the initials or unique identification code, and the specific activities of each pharmacist or pharmacy technician who performed any centralized filling or centralized processing function;

(4) Complying with federal and state laws, rules, and regulations;

(5) Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(6) Reviewing, at least annually, the written policies and procedures and documenting that review.

657—18.11 to **18.14** Reserved.

657—18.15(155A) Records. Central fill or central processing pharmacies shall maintain appropriate records that identify, by prescription drug order, the name and initials or unique identification code of each pharmacist or pharmacy technician who performs a centralized filling or centralized processing function for a prescription drug order. Originating pharmacies shall maintain appropriate records that identify, by prescription drug order, the name and initials or unique identification code of the pharmacist who performed drug use review and the pharmacist who transmitted the prescription drug order to the central fill or central processing pharmacy. These records may be maintained separately by each pharmacy or in a common electronic file as long as the data processing system is capable of producing a printout that lists the functions performed by each pharmacy and pharmacist or technician and identifies the pharmacist or technician who performed each function.

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 155A.13, and 155A.28.

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CHAPTER 19
NONRESIDENT PHARMACY PRACTICE

657—19.1(155A) Definitions.

"Board" means the Iowa board of pharmacy examiners.

"Home state" means the state in which a pharmacy is located.

"Nonresident pharmacy" means a pharmacy, including an Internet-based pharmacy, located outside the state of Iowa which delivers, dispenses, or distributes, by any method, prescription drugs, devices, or pharmacy services to an ultimate user physically located in this state.

"Nonresident pharmacy license" means a pharmacy license issued to a nonresident pharmacy.

"Pharmacy service" includes, but is not limited to, nonproduct services such as providing patient counseling and drug information, assessing health risks, and providing pharmaceutical care.

657—19.2(155A) Application and license requirements. A nonresident pharmacy shall apply for and obtain, pursuant to provisions of 657—8.35(155A), a nonresident pharmacy license from the board prior to providing prescription drugs, devices, or pharmacy services to an ultimate user in this state. Change of pharmacy name, ownership, location, or pharmacist in charge shall require a new completed application and license fee pursuant to 657—subrule 8.35(6). A nonresident pharmacy intending to close or discontinue provision of prescription drugs, devices, and pharmacy services to Iowa patients shall notify the board as provided in 657—subrule 8.35(7).

657—19.3(124,155A) Applicability of board rules. A nonresident pharmacy shall comply with all requirements of this chapter and of 657—Chapter 8 and other board rules relating to the services that are provided by the pharmacy to patients in Iowa.

19.3(1) *Type of pharmacy practice.* A nonresident pharmacy, based on the principal type of pharmacy practice, shall comply with board rules as follows:

a. A "general pharmacy" as described in 657—6.1(155A) shall comply with all requirements of 657—Chapter 6.

b. A "hospital pharmacy" as described in 657—7.1(155A), excepting licensure pursuant to Iowa Code chapter 135B, shall comply with all requirements of 657—Chapter 7.

c. A "limited use pharmacy" as described in 657—subrule 8.35(2) shall comply with all requirements of the limited use pharmacy practice.

19.3(2) *Controlled substances.* A nonresident pharmacy providing prescription drugs identified as controlled substances under Iowa Code chapter 124 shall comply with all requirements of 657—Chapter 10 except requirements for registration with the board.

19.3(3) *Compounding.* A nonresident pharmacy engaged in the compounding of drug products as defined in 657—20.2(124,126,155A) shall comply with all requirements of 657—Chapter 20.

19.3(4) *Long-term care services.* A nonresident pharmacy providing services to Iowa patients in a long-term care facility as defined in 657—23.1(155A) shall comply with all requirements of 657—Chapter 23.

19.3(5) *Electronic data.* A nonresident pharmacy utilizing any electronic data processing or transmission devices or services shall comply with all requirements of 657—Chapter 21.

657—19.4 to **19.6** Reserved.

657—19.7(155A) Confidential data. The pharmacist in charge shall be responsible for developing, implementing, and enforcing policies and procedures to ensure patient confidentiality and to protect patient identity and patient-specific information from inappropriate or nonessential access, use, or distribution pursuant to the requirements of 657—8.16(124,155A).

657—19.8(124,155A) Storage and shipment of drugs and devices. The pharmacist in charge shall be responsible for developing, implementing, and enforcing policies and procedures to ensure compliance with rules 657—8.7(155A) and 657—8.15(155A) and USP standards for the storage and shipment of

drugs and devices. Policies and procedures shall provide for the shipment of controlled substances via a secure and traceable method, and all records of such shipment and delivery to Iowa patients shall be maintained for a minimum of two years from date of delivery.

657—19.9(155A) Patient record system, prospective drug use review, and patient counseling.

19.9(1) *Patient record system.* A patient record system shall be maintained pursuant to 657—6.13(155A) for Iowa patients for whom prescription drug orders are dispensed.

19.9(2) *Prospective drug use review.* A pharmacist shall, pursuant to the requirements of 657—8.21(155A), review the patient record and each prescription drug order before dispensing.

19.9(3) *Patient counseling.* The pharmacist in charge shall be responsible for developing, implementing, and enforcing policies and procedures to ensure that Iowa patients receive appropriate counseling pursuant to the requirements of 657—6.14(155A).

657—19.10(155A) Discipline. Pursuant to 657—Chapters 35 and 36, the board may deny, suspend, or revoke a nonresident pharmacy license for any violation of Iowa Code section 155A.13A; section 155A.15, subsection 2, paragraph *"a," "b," "d," "e," "f," "g," "h,"* or *"i"*; Iowa Code chapter 124, 124A, 124B, 126, or 205; or a rule of the board.

These rules are intended to implement Iowa Code sections 124.301, 124.306, 155A.13, 155A.13A, 155A.19, and 155A.35.

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CHAPTER 20
PHARMACY COMPOUNDING PRACTICES

657—20.1(124,126,155A) Purpose and scope. The requirements of this chapter apply to the compounding of drugs by Iowa-licensed pharmacists and pharmacies and are minimum good compounding practices for the preparation of drug products for dispensing or administering to humans or animals. Pharmacists and pharmacies engaged in the compounding of drugs shall comply with all applicable provisions of state and federal laws, rules, and regulations.

657—20.2(124,126,155A) Definitions. For the purposes of this chapter, the following definitions apply:

"Bulk drug substance" means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. The term does not include intermediates used in the synthesis of such substances.

"Component" means any ingredient, other than a bulk drug substance, intended for use in the compounding of a drug product, including those ingredients that may not be identifiable in the final product.

"Compounding" means preparing, mixing, assembling, packaging, and labeling a drug or device for an identified individual patient as a result of a practitioner's prescription drug order or initiative based on the prescriber/patient/pharmacist relationship in the course of professional practice or for the purpose of, or incident to, research, teaching, or chemical analysis, and not for sale or dispensing. All compounding, regardless of the type of product, is to be done pursuant to a prescription. Compounding also includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription or in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns pursuant to subrule 20.3(3). Compounding does not include mixing or reconstituting a drug according to the product's labeling or to the manufacturer's directions.

"FDA" means the Food and Drug Administration of the U.S. Department of Health and Human Services.

"Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of the drug's or device's container. Manufacturing also includes the promotion, marketing, or preparation from bulk drug substances of commercially available products for resale by pharmacists, practitioners, or other persons.

657—20.3(124,126,155A) General requirements.

20.3(1) *Compounding commercially available product.* Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace, if the compounded product is changed to produce for that patient a significant difference, as authorized by the prescriber, between the compounded drug and the comparable commercially available drug product, or if use of the compounded product is in the best interest of the patient. "Significant difference" would include the removal of a dye for a medical reason such as an allergic reaction. When a compounded product is to be dispensed in place of a commercially available product, the prescriber and patient shall be informed that the product will be compounded.

20.3(2) *Substances and components.* Pharmacists shall receive, store, and use bulk drug substances manufactured by an establishment that is registered with the FDA under the Federal Food, Drug, and Cosmetic Act and that, if requested, will provide a valid certificate of analysis for each drug product. Certificates of analysis shall be maintained pursuant to rule 20.12(124,126,155A). Bulk drug substances to be used in compounding drugs:

a. When a monograph exists, shall comply with the applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph and the USP chapter on pharmacy compounding; or

b. If not subject to a monograph, shall be ingredients of drugs that the FDA has approved; or

c. If not subject to a monograph and not ingredients of FDA-approved drugs, shall appear on the FDA list of approved bulk drug substances not subject to a monograph; or

d. If not subject to a monograph, peer-reviewed medical literature shall support the use and, in the professional judgment of the pharmacist, demonstrate the safety and effectiveness of the substance.

20.3(3) *Prescriber/patient/pharmacist relationship.* A prescription for a compounded drug shall be authorized by the prescriber for a specific patient. Prescriptions for all products compounded at the pharmacy shall be maintained on file at the pharmacy as required by Iowa law. Pharmacists may compound drugs prior to receiving a valid prescription based on a history of receiving valid prescriptions generated solely within an established pharmacist/patient/prescriber relationship. Compounding based on a prescription history is bulk compounding and shall comply with the requirements of rule 20.11(126).

20.3(4) *Advertising and resale of compounded drug products.* The sale of compounded drug products to other pharmacies or to prescribers, except as provided in this subrule, is considered manufacturing. Pharmacists shall not offer compounded drug products to other licensed persons or commercial entities for subsequent resale except in the course of professional practice for a practitioner to administer to an individual patient. A pharmacy may sell to a hospital pharmacy a compounded drug product prepared pursuant to a prescriber's authorization for administration to a specific patient. The label affixed to the compounded drug product shall identify the pharmacy that compounded the product as the dispensing pharmacy. The original prescription drug order shall be maintained by the dispensing pharmacy. These rules shall not prohibit the hospital pharmacy from billing the patient or the patient's fiscal agent for a compounded product prepared for the patient and purchased by the hospital pharmacy pursuant to this subrule. Compounding pharmacies or pharmacists may advertise or otherwise promote the fact that they provide prescription drug compounding services. Compounding pharmacies or pharmacists shall not make a claim, assertion, or inference of professional superiority in the compounding of drug products that cannot be substantiated. All advertisements shall meet the requirements contained in 657—8.12(126,147). Nothing in these rules shall prohibit the centralized filling or processing of a prescription drug order for a compounded drug product by a central fill or processing pharmacy on behalf of an originating pharmacy as provided in 657—Chapter 18.

20.3(5) *Compounding prohibited.* Pharmacists shall not compound:

a. A drug that has been identified by the FDA as withdrawn or removed from the market because the drug was found to be unsafe or ineffective.

b. Regularly or in inordinate amounts drugs that are essentially copies of a commercially available drug product except as provided in subrule 20.3(1).

c. Drugs that have been identified by the FDA or the board as products which may not be compounded.

657—20.4(126,155A) Organization and personnel.

20.4(1) *Pharmacist responsible.* As in the dispensing of all prescription drugs, the pharmacist has the responsibility and authority to inspect and approve or reject all components, bulk drug substances, drug product containers, closures, in-process materials, and labeling. The pharmacist is also responsible for the preparation and review of all records relating to compounding to ensure that no errors have occurred in the compounding process and for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

20.4(2) *Pharmacist competence.* All pharmacists engaged in compounding shall be proficient commensurate with the level of their compounding activity. Pharmacists shall maintain proficiency through current awareness and documented training. Every pharmacist who engages in drug compounding shall be aware of, familiar with, and comply with good compounding practices and all applicable state and federal laws and regulations.

20.4(3) *Pharmacy technicians.* Pharmacy technicians may assist in the compounding of drug products, but the supervising pharmacist remains responsible for all work performed by the pharmacy technician.

20.4(4) *Protective apparel.* Personnel engaged in the compounding of drug products shall wear protective apparel as necessary to protect the individuals from chemical exposure and to protect drug products from contamination.

657—20.5(126,155A) Drug compounding facilities. Pharmacies engaged in compounding shall have a specifically designated and adequate area for the orderly placement of equipment and materials to be used to compound drugs. Sterile and nonsterile products shall not be compounded at the same time within the same area.

20.5(1) *Component and bulk drug substance storage.* Bulk drug substances and other materials used in the compounding of drug products shall be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

20.5(2) *Facility requirements.* Adequate lighting and ventilation shall be provided in all drug compounding areas. Adequate washing facilities, easily accessible to compounding areas of the pharmacy, shall be provided. These facilities shall include, but not be limited to, a sink with hot and cold running water, soap or detergent, and air dryers or single-source towels.

20.5(3) *Facility maintenance.* All areas used for the compounding of drug products shall be maintained in a clean and sanitary condition and in a good state of repair and shall be free of infestation by insects, rodents, and other vermin. Sewage, trash, and other refuse in and from the pharmacy and immediate drug compounding areas shall be maintained and disposed of in a timely, safe, and sanitary manner.

657—20.6(126,155A) Sterile products and radiopharmaceuticals.

20.6(1) *Sterile products.* If sterile products are being compounded, the requirements of 657—Chapter 13, in addition to the requirements of this chapter, shall be met.

20.6(2) *Radiopharmaceuticals.* If radiopharmaceuticals are being compounded, the requirements of 657—Chapter 16 shall be met.

657—20.7 Reserved.

657—20.8(126,155A) Equipment. Equipment used in the compounding of drug products shall be of appropriate design and adequate size and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be of suitable composition so that surfaces that come into contact with components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond that desired.

20.8(1) *Equipment maintenance.* Equipment and utensils used for compounding shall be cleaned and sanitized prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond that desired. In the case of equipment, utensils, and containers or closures used in the compounding of sterile drug products, cleaning, sterilization, and maintenance procedures as set forth in 657—Chapter 13 shall be followed.

20.8(2) *Specialized equipment.* If drug products with special precautions to prevent contamination are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, shall be utilized in order to prevent cross-contamination.

20.8(3) *Use of automated equipment.* Automatic, mechanical, or electronic equipment, or other types of equipment or related systems that will perform a function satisfactorily, may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected and calibrated if necessary to ensure proper performance.

20.8(4) *Equipment storage.* Equipment and utensils used for compounding drugs shall be stored in a manner to protect them from contamination.

657—20.9(126,155A) Control of bulk drug substances, components, containers, and closures. Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety,

identity, strength, quality, or purity of the compounded drug beyond the desired result. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to ensure that the containers and closures are suitable for their intended use.

20.9(1) *Storage.* Components, bulk drug substances, drug product containers, closures, and bagged or boxed parts of drug product containers and closures used in the compounding of drug products shall be handled and stored in a manner to prevent contamination and to permit inspection and unhindered cleaning of the work area, including floors. Components, bulk drug substances, drug product containers, and closures for use in the compounding of drug products shall be rotated so that the oldest stock is used first.

20.9(2) *Sterile product containers and closures.* Drug product containers and closures intended for use in the compounding of sterile products shall be handled, sterilized, and stored in compliance with the requirements of 657—Chapter 13. Procedures shall be written, implemented, and followed for cleaning, sterilizing, and processing drug product containers and closures to remove pyrogenic properties.

657—20.10(124,126,155A) Drug compounding controls. Accountability for quality control is the responsibility of the compounding pharmacist.

20.10(1) *Procedures required.* Procedures for the compounding of drug products shall be written, implemented, and followed to ensure the safety, identity, strength, quality, and purity of the finished product. Such procedures shall include a listing of the bulk drug substances and components, their amounts in weight or volume, the order of bulk drug substance and component addition, and a description of the compounding processes. All equipment, utensils, and the container closure system relevant to the sterility and stability of the intended use of the compounded drug product shall be listed as necessary.

20.10(2) *Accuracy.* Components and bulk drug substances used in the compounding of drug products shall be accurately weighed, measured, or subdivided as appropriate. These operations shall be verified at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component or bulk drug substance is removed from the original container and stored in another container, the new container shall be identified with the name and lot number of the component or bulk drug substance.

20.10(3) *Record.* A production record shall be prepared and kept for each drug product compounded for an individual patient. The record shall include the following information:

a. Production date;

b. List of ingredients and quantity of each ingredient used;

c. Initials of each person involved in each of the compounding steps;

d. Initials of each pharmacist verifying each of the compounding steps;

e. Internal control or prescription number and, if the prescription is filled using a product compounded in bulk pursuant to rule 20.11(126), the internal control number assigned to the batch and recorded in the batch production record.

20.10(4) *Product testing and examination.* To ensure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established, implemented, and followed that describe the tests or examinations to be conducted on the product being compounded to monitor the output and to validate the performance of compounding processes that may be responsible for causing variability in the final drug product. Control procedures shall include, but are not limited to, the following as appropriate:

a. Capsule weight variation;

b. Adequacy of mixing to ensure uniformity and homogeneity;

c. Clarity, completeness, or pH of solutions.

20.10(5) *Sterilization.* Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purported to be sterile, including validation of any sterilization process, shall be established and followed.

20.10(6) *Label information required.* The label affixed to or on the dispensing container of any compounded drug product dispensed by a pharmacy pursuant to a prescription drug order, excluding a sterile product compounded pursuant to 657—Chapter 13, shall bear the following:

a. Serial number (a unique identification number of the prescription);

b. The name, telephone number, and address of the pharmacy;

c. The name of the patient or, if such drug is prescribed and compounded for an animal, the species of the animal and the name of its owner;

d. The name of the prescribing practitioner;

e. The date the compounded drug product is dispensed;

f. The directions or instructions for use, including precautions to be observed;

g. The name and quantity or percentage of each bulk drug substance (active ingredient) contained in the compounded drug product. The use of auxiliary labels to accommodate this information is acceptable;

h. The initials or other unique identification of the dispensing pharmacist.

20.10(7) *Labeling—expiration date.* When applicable, the compounded product shall be labeled with an expiration date based on published data. When such data is unavailable, expiration dating shall be based on professional judgment or appropriate testing.

20.10(8) *Labeling and control of excess products.* When a quantity of a compounded drug product is prepared in excess of that to be initially dispensed, the excess product shall be labeled, stored, and accounted for pursuant to rule 20.11(126).

657—20.11(126) Bulk compounding.

20.11(1) *Master formula record.* Pursuant to the provisions of subrule 20.3(3), pharmacies may compound drugs in bulk quantities for subsequent prescription labeling and dispensing. For each drug product compounded in bulk quantity, a master formula record containing the following information shall be prepared:

a. Name of the product;

b. Specimen or copy of label;

c. List of ingredients and quantities;

d. Description of container used;

e. Compounding instructions, procedures and specifications.

20.11(2) *Production record.* For each batch of drug product compounded, a production record containing the following information shall be prepared and maintained:

a. The information from the master formula record;

b. Records of each step in the compounding process including:

(1) Preparation date;

(2) Identification of ingredients (including lot numbers);

(3) Quantities of ingredients used;

(4) Initials of person completing each step;

(5) Initials of pharmacist verifying each step;

c. Expiration/beyond-use date;

d. Internal control number;

e. Total yield.

20.11(3) *Label information.* For each batch of drug product compounded, labels containing the following information shall be prepared and affixed to each container:

a. Drug product name or formula;

b. Dosage form;

c. Strength;

d. Quantity per container;

e. Internal control number;

f. Expiration/beyond-use date.

657—20.12(124,126,155A) Records. All records required by this chapter shall be retained as the original records and shall be readily available at the pharmacy for inspection and photocopying by agents of the board or other authorized authorities for at least two years following the date of the record.

These rules are intended to implement Iowa Code sections 124.302, 124.303, 124.306, 124.308, 124.501, 126.9, 126.10, 126.18, 155A.2, 155A.28, 155A.33, and 155A.35.

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CHAPTER 21
ELECTRONIC DATA IN PHARMACY PRACTICE

657—21.1(124,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Electronic signature" means a confidential personalized digital key, code, or number used for secure electronic data transmissions which identifies and authenticates the signatory.

"Electronic transmission" means the transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment. "Electronic transmission" includes, but is not limited to, transmission by facsimile machine, transmission to a printer as provided in subrule 21.7(3), and transmission by computer link, modem, or other communication device.

"Prescription drug order" or *"prescription"* means a lawful order of a practitioner for a drug or device for a specific patient that is communicated to a pharmacy, regardless of whether the communication is oral, electronic, or in printed form.

657—21.2(124,155A) System security and safeguards. To maintain the integrity and confidentiality of patient records and prescription drug orders, any system or computer utilized shall have adequate security including system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescription drug orders. Once a drug or device has been dispensed, any alterations in either the prescription drug order data or the patient record shall be documented and shall include the identification of all pharmacy personnel who were involved in making the alteration as well as the responsible pharmacist.

657—21.3(124,155A) Verifying authenticity of an electronically transmitted prescription. The pharmacist shall ensure the validity of the prescription as to its source of origin. Measures to be considered in authenticating prescription drug orders received via electronic transmission or signed utilizing an electronic signature include:

1. Maintenance of a practitioner number reference or electronic signature file.
2. Verification of the telephone number of the originating facsimile equipment or oral communication device.
3. Telephone verification with the practitioner's office that the prescription was both issued by the practitioner and transmitted by the practitioner or the practitioner's authorized agent.
4. Other efforts which, in the professional judgment of the pharmacist, may be necessary to ensure that the transmission was initiated by the prescriber.

657—21.4(124,155A) Automated data processing system. An automated data processing system may be used, subject to the requirements contained in this rule, for the storage and retrieval of original and refill information for prescription orders.

21.4(1) *On-line retrieval of prescription information.* Any computerized system shall provide on-line retrieval (via CRT display and hard-copy printout) of original prescription order information and refill history information. This shall include, but is not limited to, the following:

a. Original prescription number;
b. Date of issuance of the original prescription order by the practitioner;
c. Date and quantity of initial fill;
d. Date and quantity of each refill or partial fill, if applicable;
e. Full name and address of the patient;
f. Name, address, and, if a controlled substance, DEA registration number of the prescriber;
g. Name, strength, dosage form, quantity of the drug or device prescribed, and the total number of refills authorized by the prescribing practitioner; and
h. For each fill or refill, the identification code, name, or initials of the dispensing pharmacist.

21.4(2) *Printout of prescription fill data.* Any computerized system shall have the capability of producing a printout of any prescription fill data the user pharmacy is responsible for maintaining or

producing under state and federal rules and regulations. This would include a refill-by-refill audit trail for any specified strength and dosage form of any prescription drug by brand or generic name or both. In any computerized system employed by a user pharmacy, the central record-keeping location must be capable of providing the printout to the pharmacy within 48 hours. The printout shall include the following:

a. Name of the prescribing practitioner;
b. Name and address of the patient;
c. Quantity dispensed on each fill;
d. Date of dispensing for each fill;
e. Name or identification code of the dispensing pharmacist; and
f. The number of the original prescription order.

21.4(3) *Auxiliary procedure for system downtime.* In the event that a pharmacy utilizing a computerized system experiences system downtime, the pharmacy shall have an auxiliary procedure that will be used for documentation of fills of prescription orders. This auxiliary procedure shall ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry when the computer system is again available for use. As soon as reasonably possible upon resuming use of the computerized system, entry of all appropriate data accumulated during the system downtime shall be completed.

657—21.5(124,155A) Pharmacist verification of controlled substance refills—daily printout or logbook. The individual pharmacist who makes use of the system shall provide documentation of the fact that the refill information entered into a computer each time the pharmacist refills an original prescription order for a controlled substance is correct. If the system provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by each individual pharmacist who refilled a controlled substance prescription order. Each individual pharmacist must verify that the data indicated is correct and sign this document in the same manner as the pharmacist would sign a check or legal document (e.g., J. H. Smith or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data shall be generated by and available at each pharmacy using a computerized system within 48 hours of the date on which the refill was dispensed. The printout shall be verified and signed by each pharmacist involved with such dispensing.

In lieu of preparing and maintaining printouts as provided above, the pharmacy may maintain a bound logbook or separate file. The logbook or file shall include a statement signed each day by each individual pharmacist involved in each day's dispensing that attests to the fact that the refill information entered into the computer that day has been reviewed by the pharmacist and is correct as shown. Pharmacist statements shall be signed in the manner previously described. The log book or file shall be maintained at the pharmacy for a period of two years after the date of dispensing the appropriately authorized refill.

657—21.6 Reserved.

657—21.7(124,155A) Electronically prepared prescriptions. A prescriber may initiate and authorize a prescription drug order utilizing a computer or other electronic communication or recording device. The prescription drug order shall contain all information required by Iowa Code section 155A.27. 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 21.3(124,155A).

21.7(1) *Controlled substances.* A prescription for a controlled substance prepared pursuant to this rule may be transmitted to a pharmacy via facsimile transmission as provided by rule 21.9(124,155A) or rules 21.12(124,155A) through 21.16(124,155A). The transmitted prescription shall include the prescriber's original signature or electronic signature.

21.7(2) *Noncontrolled prescription drugs.* A prescription for a noncontrolled prescription drug prepared pursuant to this rule may be transmitted to a pharmacy via computer-to-computer transmission as provided in rule 21.8(124,155A) or via facsimile transmission as provided in rule 21.9(124,155A). The transmitted prescription shall include the prescriber's original signature or electronic signature.

21.7(3) *Printed (hard-copy) prescriptions.* A prescription prepared pursuant to this rule may be printed by the prescriber or prescriber's agent for delivery to a pharmacy.

a. A prescription for a controlled substance shall include the prescriber's original signature.

b. If the prescriber authenticates a prescription for a noncontrolled prescription drug utilizing an electronic signature, the printed prescription shall be printed on security paper that is designed to prevent photocopying or other duplication of the printed prescription by prominently disclosing the word "void" or "copy" on the duplication or by including a watermark or background that will not appear on duplication. If a watermark or background is used, the prescription shall include a statement that unless the watermark or background appears, the prescription is not valid.

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).
[**ARC 7636B**, IAB 3/11/09, effective 4/15/09]

657—21.8(124,155A) Computer-to-computer transmission of a prescription. Prescription drug orders, excluding orders for controlled substances, may be communicated directly from a prescriber's computer to a pharmacy's computer prescription processing system by electronic transmission. 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 21.3(124,155A).

21.8(1) *Secure transmission and patient's choice.* Orders shall be sent only to the pharmacy of the patient's choice, and no unauthorized intervening person or other entity shall change the content of the prescription drug order or compromise its confidentiality during the transmission process.

21.8(2) *Information required.* The electronically transmitted order shall identify the transmitter's telephone number for verbal confirmation, the time and date of transmission, and the pharmacy intended to receive the transmission as well as any other information required by federal or state laws, rules, or regulations.

21.8(3) *Who may transmit.* Orders shall be initiated only by an authorized prescriber and shall include the prescriber's electronic signature. Orders may be transmitted by the prescriber or the prescriber's agent.

21.8(4) *Original prescription.* The electronic transmission shall be deemed the original prescription drug order provided it meets the requirements of this rule.

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 by name and title 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 not apply to a prescription drug order transmitted pursuant to 657—subrule 8.15(1), paragraph *"d."*
[**ARC 7636B**, IAB 3/11/09, effective 4/15/09; **ARC 8171B**, IAB 9/23/09, effective 10/28/09]

657—21.10 and **21.11** Reserved.

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.
[**ARC 7636B**, IAB 3/11/09, effective 4/15/09]

657—21.13(124,155A) Prescription drug orders for Schedule II controlled substances—emergency situations. A pharmacist may in an emergency situation as defined in 657—subrule 10.22(1) dispense Schedule II controlled substances pursuant to an electronic transmission to the pharmacy of a written, signed prescription from the prescribing practitioner pursuant to the requirements of 657—10.22(124). The facsimile or a print of the electronic transmission shall serve as the temporary written record required by 657—subrule 10.22(2).

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.
[**ARC 7636B**, IAB 3/11/09, effective 4/15/09]

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.

21.15(1) *Original prescription.* The facsimile serves as the original written prescription.

21.15(2) *Information required.* The patient's address on the prescription shall indicate that the address location is a long-term care facility.
[**ARC 7636B**, IAB 3/11/09, effective 4/15/09]

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.

21.16(1) *Original prescription.* The facsimile serves as the original written prescription.

21.16(2) *Information required.* The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient.

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

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CHAPTER 22
UNIT DOSE, ALTERNATIVE PACKAGING, AND EMERGENCY BOXES

657—22.1(155A) Unit dose dispensing systems.

22.1(1) *Definitions.* For the purpose of this rule, the following definitions shall apply:

"Single unit package" means a package that contains one discrete pharmaceutical dosage form.

"Unit dose dispensing system" means a drug distribution system utilizing single unit, unit dose, or unit of issue packaging in a manner that helps reduce or remove traditional drug stocks from resident care areas and enables the selection and distribution of drugs to be pharmacy-based and controlled.

"Unit dose package" means a package that contains that particular dose of a drug ordered for the patient for one administration time. A unit dose package is not always a single unit package.

"Unit of issue package" means a package that provides multiple units or doses attached to each other but separated in a card or specifically designed container.

22.1(2) *General procedures.* The following will apply when a unit dose dispensing system is employed:

a. The pharmacist shall be responsible for determining the classification for containers, as set by USP General Chapter 671, used by the pharmacy to repackage nonsterile drugs into single unit, unit dose, or unit of issue packaging. This classification shall be used to determine maximum expiration dating for repackaging set forth in subrule 22.1(4).

b. Established written policies and procedures shall be available in the pharmacy for inspection by the board or its agents which specify the drug categories, specific drugs, or dosage forms which will not be dispensed under the particular unit dose dispensing system employed.

c. Those drugs not dispensed under a unit dose dispensing system shall be dispensed in accordance with the packaging requirements of the federal Food and Drug Administration (FDA).

22.1(3) *Labeling requirements.*

a. Labeling for single unit or unit dose packaging shall comply with the following:

(1) Doses packaged by the manufacturer or distributor shall be properly labeled according to federal Food and Drug Administration (FDA) requirements.

(2) Doses packaged by the pharmacy for use beyond a 24-hour period shall be labeled and packaged according to the prepackaging requirements established in subrule 22.3(2).

b. Labeling for unit of issue packages shall contain the following information:

(1) Name, strength, and expiration date of drug when the packages are utilized for floor stock in an institutional setting.

(2) Name and room or bed number of patient, the name of prescribing practitioner, the name and strength of drug, directions for use, and name and address of the dispensing pharmacy, when the packages are utilized for patients in an institutional setting. Room or bed number, the name of prescribing practitioner, and the name and address of the dispensing pharmacy are not required if this information appears on a medication administration record used by the institution.

(3) Unit of issue packages dispensed to patients on an outpatient basis or in a noninstitutional setting shall be considered prescription containers and shall be labeled in accordance with 657—subrule 6.10(1).

c. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the label must identify the generic drug and may identify the brand name drug for which the selection is made. The dual identification allowed under this paragraph must take the form of the following statement on the label: "(generic name) Generic for (brand name product)".

d. The labeling requirements of paragraphs *"a"* and *"b"* of this subrule shall not apply to the special circumstances identified in rule 657—23.13(124,155A).

e. Those drugs not dispensed under a unit dose dispensing system shall be labeled in accordance with the requirements of subrule 22.5(5) or 657—subrule 6.10(1) as appropriate.

22.1(4) *Expiration dating.* Expiration dating for nonsterile drugs repackaged by the pharmacy into single unit, unit dose, or unit of issue packages shall meet the following conditions:

a. Not exceed 90 days from the date of repackaging except as provided in paragraph 22.1(4)*"c."*

b. Not exceed the manufacturer's original expiration date.

c. May exceed 90 days from the date of repackaging provided that each of the following conditions is met:

(1) The container is classified according to USP General Chapter 671 as being Class A or Class B for oral solid dosage forms or is a tight container for liquid dosage forms.

(2) The container is light resistant when the manufacturer has labeled the product "sensitive to light."

(3) The expiration date is not greater than 12 months.

d. Drugs or dosage forms having known stability problems are assigned an expiration date of less than 90 days or are not repackaged as determined by policies developed by the pharmacy.

22.1(5) *Packaging requirements.* Packaging for all nonsterile drugs stored and dispensed in single unit, unit dose, or unit of issue packages shall:

a. Preserve and protect the identity and integrity of the drug from the point of packaging to the point of patient administration.

b. When packaged by the manufacturer or distributor, be in accordance with federal Food and Drug Administration (FDA) requirements.

c. When in single unit and unit dose packages prepackaged by the pharmacy for use beyond 24 hours, be in accordance with rule 22.3(126).

d. Be clean and free of extraneous matter.

22.1(6) *Return of drugs.* Under no circumstances shall a pharmacist accept for reuse, except to the same patient, any previously dispensed controlled substances. Drugs, excluding controlled substances, dispensed in single unit, unit dose, or unit of issue packaging in compliance with subrules 22.1(2) to 22.1(5) may be returned to the pharmacy stock and reissued provided that:

a. The expiration dating information is retrievable and identifiable.

b. Drugs returned from unit of issue packaging are kept separate according to manufacturer's lot number and the repackaged expiration date assigned pursuant to subrule 22.1(4). If, however, the pharmacy's recall policy states that all lots of a drug shall be considered part of the recall due to unknown manufacturer's lot numbers, drugs returned to stock from unit of issue packaging shall be kept separate according to the pharmacy's repackaged expiration date.

c. The drugs were stored under proper storage conditions.

d. The drugs are returned to the pharmacy in the original packaging as when dispensed.

e. The pharmacy includes in written policies and procedures the manner in which returned drugs will be recorded or identified.

This rule is intended to implement Iowa Code section 155A.36.

657—22.2 Reserved.

657—22.3(126) Prepackaging.

22.3(1) *Control record.* Pharmacies may prepackage and label drugs in convenient quantities for subsequent labeling and dispensing. Such drugs shall be prepackaged by or under the direct supervision of a pharmacist. The supervising pharmacist shall be responsible for the preparation and maintenance of a packaging control record containing the following information:

a. Date.

b. Identification of drug.

(1) Name of drug.

(2) Dosage form.

(3) Manufacturer.

(4) Manufacturer's lot number.

(5) Strength.

(6) Expiration date.

c. Container specification.

d. Copy of a sample label.

e. Initials or unique identification of the packager.

f. Initials or unique identification of the supervising pharmacist.

g. Quantity per container.

h. Internal control number or date.

22.3(2) *Label information.* Each prepackaged container shall bear a label containing the following information:

a. Name of drug.

b. Strength.

c. Internal control number or date.

d. Expiration date consistent with USP standards.

e. Auxiliary labels, as needed.

22.3(3) *Labeling for delivery.* Prior to the delivery of a prepackaged drug to a patient, an appropriate label shall be affixed to the drug container pursuant to the labeling requirements of the appropriate pharmacy practice rules.

This rule is intended to implement Iowa Code sections 126.10 and 126.11.

657—22.4 Reserved.

657—22.5(126,155A) Patient med paks. In lieu of dispensing prescribed drug products in conventional prescription containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber, provide a customized patient medication package (patient med pak) pursuant to the requirements of this rule.

22.5(1) *Definition.* A patient med pak is a customized patient medication package prepared for a specific patient which comprises a series of immediate containers containing prescribed solid oral dosage forms, each container being labeled with the time or the appropriate period for the patient to take its contents.

22.5(2) *General procedures.* The following shall apply when patient med paks are employed:

a. The pharmacist shall be responsible for determining the classification, as directed by USP General Chapter 671, for containers used by the pharmacy to repackage nonsterile drugs into patient med paks.

b. Packaging for all nonsterile solid oral dosage forms stored and dispensed in patient med paks shall:

(1) Preserve and protect the identity and integrity of the drug from the point of packaging to the point of administration, and

(2) Be clean and free of extraneous matter when the drugs are placed into the package.

c. Drugs dispensed in patient med paks to patients may not be returned to the pharmacy stock and reissued except to the same patient as provided in subrule 22.5(4).

d. There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus, the patient med pak, if it does not meet child-resistant standards, shall be placed in an outer package that does comply, or the necessary consent of the purchaser or physician to dispense in a container not intended to be child-resistant shall be obtained.

22.5(3) *Reuse of containers.* Notwithstanding requirements that all prescription drugs be dispensed in a new container conforming with standards established in the official compendia, a pharmacist may dispense and refill a prescription for nonliquid oral products in a clean patient med pak provided:

a. A patient med pak is reused only for the same patient; and

b. No more than a one-month supply is dispensed at one time.

22.5(4) *Repackaging of patient med paks.* In the event a drug is added to or discontinued from a patient's drug regimen, the pharmacist may repackage the patient's med pak and either add to or remove from the patient's drugs packaged as ordered by the prescriber. Drugs returned by the patient for repackaging shall be reused by the pharmacist in the design of the new patient med pak, and any drug removed from the new drug regimen shall either be disposed of in compliance with board rules or returned, properly labeled, to the patient. Under no circumstances shall a drug within a container of a patient med pak be returned to the pharmacy stock.

22.5(5) *Labeling requirements.*

a. Except as provided in subrule 22.5(6), the patient med pak shall be labeled with the following:

(1) The name of the patient;

(2) The unique identification number for the patient med pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(3) The name, strength, dosage form, and total quantity of each drug product contained therein;

(4) The directions for use for each drug product contained therein;

(5) The name of the prescriber of each drug product;

(6) The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak;

(7) The name, address, and telephone number of the pharmacy; and

(8) The initials or unique identification of the responsible pharmacist.

b. The patient med pak shall be accompanied by a patient package insert, in the event that any drug contained therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the pharmacist for the total patient med pak.

c. If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying the patient, the unique identification number for the patient med pak, and the name and telephone number of the dispensing pharmacy.

d. If a pharmacist selects a generically equivalent drug product for a brand-name drug product prescribed by a practitioner, the label must identify the generic drug and may identify the brand-name drug for which the selection is made. The dual identification allowed under this paragraph must take the form of the following statement on the label: "(generic name) Generic for (brand-name product)".

22.5(6) *Alternate labeling.* If the patient med pak container is not of sufficient size to accommodate the label information as required in subrule 22.5(5) in a legible font, a patient package insert shall be prepared and delivered with the patient med pak. The patient package insert shall contain all label information required in subrule 22.5(5). In such case, the label affixed to the patient med pak shall minimally include:

a. The name of the patient;

b. The unique identification number for the patient med pak;

c. The beyond-use date assigned to the patient med pak;

d. A statement directing the patient or patient's caregiver to the patient package insert; and

e. The name and telephone number of the dispensing pharmacy.

22.5(7) *Expiration/beyond-use dating.* Beyond-use date or period of time shall be not longer than the shortest recommended beyond-use date for any dosage form included therein or not longer than 60 days from the date of preparation of the patient med pak, whichever is shorter. In no event shall the beyond-use date exceed the shortest expiration date on the original manufacturer's bulk containers for the dosage forms included in the patient med pak. Alternatively, the package label shall state the date of the prescriptions or the date of preparation of the patient med pak, provided the package is accompanied by a record indicating the start date and the beyond-use date.

22.5(8) *Record keeping.*

a. The record of each patient med pak shall contain, at a minimum:

(1) The name and address of the patient;

(2) A unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(3) A unique identification number for the patient med pak;

(4) Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;

(5) The date of preparation of the patient med pak and the beyond-use date that was assigned;

(6) Any special labeling instructions; and

(7) The name, unique identification, or initials of the responsible pharmacist.

b. The record of the individual prescription drug orders for each of the drug products packaged in a patient med pak shall include the unique identification number for the patient med pak wherein the prescription drug is dispensed.

This rule is intended to implement Iowa Code sections 126.10, 126.11, and 155A.28.

657—22.6 Reserved.

657—22.7(124,155A) Emergency/first dose drug supply. In any facility registered with the board under Iowa Code chapter 124 that does not have an institutional pharmacy, drugs may be supplied in one or more emergency/first dose drug supply containers located at the facility, provided that the emergency/first dose drug supply meets the requirements of this rule. The use of drugs from the emergency/first dose drug supply shall be limited to authorized personnel. The pharmacy supplying the emergency/first dose drug supply is responsible for verifying the qualifications of the facility.

22.7(1) *Emergency/first dose drug supplies.* All contents of the emergency/first dose drug supply shall be provided by one 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. The provider pharmacy 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, 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 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 and the facility to make drugs available, and this supply 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; 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 are the responsibility of the pharmacy and, therefore, shall not be used or altered in any way except as provided in this rule.

22.7(2) *Storage.* The emergency/first dose drug supply shall be stored in an area suitable to prevent unauthorized access and to ensure a proper environment for preservation of drugs contained therein as required in official compendia. The provider pharmacist is responsible for establishing procedures to maintain the security of the emergency/first dose drug supply.

22.7(3) *Labeling—exterior.* The exterior of an emergency/first dose drug supply shall be labeled clearly and shall unmistakably indicate that it is an emergency/first dose drug supply. Such label shall also contain a listing of the name, strength, and quantity of each drug contained therein and an expiration date of the supply based upon the earliest expiration date of any drug contained in the supply.

22.7(4) *Labeling—interior.* All drugs contained in the emergency/first dose drug supply shall be labeled in accordance with subrule 22.3(2) or 22.1(3), as appropriate.

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.

22.7(6) *Notifications.* Whenever an emergency/first dose drug supply is opened or has expired, the provider pharmacy shall be notified and the pharmacist shall be responsible for replacing the drug within 72 hours to prevent risk of harm to patients. Policy must be developed by the provider pharmacist to address notification, record keeping, and documentation procedures for use of the supply.

22.7(7) *Procedures.*

a. The consultant or provider pharmacist shall, in communication with the director of nursing of the facility and the medical director of the facility, or their respective designees, develop and implement written policies and procedures to ensure compliance with this rule.

b. The provider pharmacy shall keep a record of each prescription drug stored in the emergency/first dose drug supply and the number of doses provided.

c. The facility shall keep a complete record of the use of prescription drugs from the emergency/first dose drug supply for two years following such use. The record shall include the patient's name, the date of use, the name of the drug used, the strength of the drug, the number of doses used, the name of the prescriber authorizing the administration, and the initials or unique identification of the person administering the dose.

d. The drugs maintained in the emergency/first dose drug supply shall be available for the emergency pharmaceutical care of all facility patients, without penalty or discrimination. If a service charge is assessed for the administration of a drug from the emergency/first dose drug supply, the same reasonable service charge shall be assessed to each patient to whom a drug from the emergency/first dose drug supply is administered, regardless of the patient's choice of pharmacy for pharmaceutical services.

This rule is intended to implement Iowa Code sections 124.301, 124.306, 155A.13, and 155A.15.

657—22.8 Reserved.

657—22.9(155A) Home health agency/hospice emergency drugs. Recognizing the emergency and unanticipated need for drugs to be available to qualified individuals authorized to administer drugs and employed by a home health agency or hospice, an Iowa-licensed pharmacy may provide an emergency drug supply pursuant to this rule. Such qualified individuals may carry the emergency drug supply. An inpatient hospice facility may have an emergency drug supply provided by an Iowa-licensed pharmacy pursuant to rule 22.7(124,155A), which supply may be maintained within the facility.

22.9(1) *Contract.* A written contract shall exist between the home health agency or hospice and the pharmacist in charge of the Iowa-licensed pharmacy. This contract shall be available for review by the board or its authorized agent upon request.

22.9(2) *Ownership retained.* The drugs included in this emergency supply shall remain the property of and under the responsibility of the Iowa-licensed provider pharmacy.

a. The pharmacist shall ensure that each portable container of emergency drugs is sealed in such a manner that a tamperproof seal must be broken to gain access to the drugs.

b. Each portable container of emergency drugs shall be labeled on the outside of the container with a list of the contents and the earliest expiration date.

22.9(3) *Removal of drugs.* All drugs shall be administered only on prior prescribers' order or by protocol approved by the agency's medical director or appropriate committee. Drugs administered from the emergency supply shall be replaced by submitting a prescription or medication order for the used item to the provider pharmacy within a reasonable time of administration.

22.9(4) *Records.* All records of drugs administered from the emergency supply shall be maintained as required by law. If a container of an injectable product is opened and partially used, any unused portion shall be immediately discarded and appropriately documented.

22.9(5) *Drugs included.* The provider pharmacist and the director of the home health agency or hospice, or their respective designees, shall jointly determine a list of drugs necessary for prompt use in the care of patients served by the home health agency or hospice and that will be available in the emergency drug supply. Drugs shall be listed by identity and quantity and shall be periodically reviewed in accordance with policy.

22.9(6) *Policies and procedures.* The pharmacist in charge of the provider pharmacy and the home health agency or hospice shall develop policies and procedures to address storage conditions and security for drugs and kit maintenance. Outdated, expired drugs shall be properly disposed of by the pharmacy.

22.9(7) *Responsibility for compliance.* The provider pharmacy is responsible to ensure compliance with this rule, and any abuse or misuse of the intent of this rule shall be immediately reported to the board.

This rule is intended to implement Iowa Code sections 155A.4, 155A.13, and 155A.15.

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CHAPTER 23
LONG-TERM CARE PHARMACY PRACTICE

657—23.1(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Consultant pharmacist" in a long-term care facility means a pharmacist licensed to engage in the practice of pharmacy in this state who is responsible for developing, coordinating, and supervising pharmaceutical services in a long-term care facility on a regularly scheduled basis. A consultant pharmacist:

1. Reviews the distribution and storage of drugs and devices and assists facilities in establishing the policies and procedures for the distribution and storage of drugs and devices and makes appropriate recommendations to the facility and the provider pharmacist;
2. Monitors the therapeutic response and utilization of all drugs and devices prescribed for each resident. The following shall be used as minimum guidelines supplementing the pharmacist's professional expertise:
   - Regulations and interpretive guidelines of the Centers for Medicare and Medicaid Services, if applicable;
   - Rules of the Iowa department of inspections and appeals; and
   - Other state rules and regulations;
3. Serves as a resource for pharmacy-related education services within the facility;
4. Participates in quality management of resident care in the facility;
5. Communicates with the provider pharmacist regarding areas of mutual concern and resolution thereof.

"Long-term care facility" or *"facility"* means:

1. A facility licensed by the Iowa department of inspections and appeals under Iowa Code chapter 135C or Iowa Code chapter 135H;
2. A hospital-based long-term care unit certified under 42 CFR, Part 483, Subpart B;
3. An inpatient hospice certified under 42 CFR, Part 418;
4. A group living facility wherein health care related services are provided by the facility; or
5. A health care facility registered with the board under Iowa Code chapter 124.

"Long-term care pharmacy" or *"provider pharmacy"* means a hospital pharmacy, a general pharmacy, a limited use pharmacy, or a nonresident pharmacy in which drugs, chemicals, or poisons are prepared, compounded, dispensed, vended, distributed, or sold on a regular and recurring basis to or for the use of residents of a long-term care facility and from which related pharmacy services are delivered.

"Medication order," as used in these rules, means a written order from a practitioner or an oral order from a practitioner or the practitioner's authorized agent for administration of a drug or device. For purposes of this chapter, "medication order" includes a prescription.

"Provider pharmacist" means a pharmacist licensed to engage in the practice of pharmacy who is employed by or contracted to a long-term care pharmacy or a provider pharmacy and who is responsible for supervising the accurate dispensing and proper delivery of drugs and devices to a long-term care facility located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping, and prospective drug utilization review in compliance with all federal and state laws and regulations.

"Single unit package" means a package that contains one discrete pharmaceutical dosage form.

"Unit dose dispensing system" means a drug distribution system utilizing single unit, unit dose, or unit of issue packaging in a manner that helps reduce or remove traditional drug stocks from resident care areas and enables the selection and distribution of drugs to be pharmacy-based and controlled.

"Unit dose package" means a package that contains that particular dose of a drug ordered for a resident for one administration time. A unit dose package is not always a single unit package.

"Unit of issue package" means a package that provides multiple units or doses attached to each other but separated in a card or specifically designed container.

657—23.2(124,155A) Applicability of rules. Nothing in these rules shall be deemed to constitute a waiver or abrogation of any of the provisions of board rules or other applicable provisions of state and federal laws and rules, nor should these rules be construed as authorizing or permitting any person not licensed as a pharmacist to engage in the practice of pharmacy.

657—23.3(124,155A) Freedom of choice. Pursuant to 657—subrule 8.11(5), no pharmacist or pharmacy shall participate in any agreement or plan that infringes on any resident's right to freedom of choice as to the provider of pharmacy services. A resident in a long-term care facility shall have a choice of long-term care pharmacy so long as the pharmacy's drug delivery system provides for the timely delivery of drugs compatible with the established system currently used by the facility. Determination of compatibility may consider medication administration, accessibility, and payment system.

657—23.4(124,155A) Pharmacy responsibilities. The long-term care pharmacy shall be responsible for:

1. Providing drugs pursuant to a medication order for an individual resident, properly labeled for that resident, as addressed in rule 657—22.1(155A) or 23.13(124,155A).
2. Dispensing drugs for residents of long-term care facilities consistent with the drug distribution system described in the facility's policies and procedures.
3. Affixing labels to each container of drugs for residents in long-term care facilities, in compliance with rule 657—22.1(155A), 23.13(124,155A), or 23.14(124,155A).
4. Maintaining records of all transactions of the long-term care pharmacy as may be required by law and maintaining accurate control over and accountability for all drugs and prescription devices.
5. Developing a drug recall procedure that protects the health and safety of residents including immediate discontinuation of any recalled drug or device and subsequent notification of the prescriber and director of nursing of the facility.
6. Providing a 24-hour emergency service procedure either directly or by contract with another pharmacy.
7. Reviewing patient profiles to ensure the appropriateness of therapy for that resident and the compatibility of the drug and dosage for that resident when processing new medication orders.
8. Providing sufficient and accurate information to facility staff regarding the appropriate administration and use of all dispensed drugs and devices.
9. Communicating with the consultant pharmacist and the facility regarding concerns and resolution thereof.

657—23.5(124,155A) Emergency drugs. A supply of emergency drugs may be provided by one long-term care pharmacy 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 emergency box or stat drug box, 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.

657—23.6(124,155A) Space, equipment, and supplies. Each pharmacy serving a long-term care facility shall have adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy and to meet the needs of the residents served. The pharmacy shall comply with all reference, environment, and equipment requirements contained in rules 657—6.3(155A) and 657—8.5(155A).

657—23.7(124,155A) Policies and procedures. Policies and procedures shall be formulated to cover the provider pharmacy's packaging and dispensing responsibilities to the residents of the long-term care facility. The policies and procedures shall be maintained at the provider pharmacy and shall be available to the facility and the consultant pharmacist. Policies and procedures shall include, at a minimum:

1. Methods used to dispense and deliver drugs and devices to the facility in a timely fashion;
2. Proper notification to the facility when a drug or device is not readily available;
3. Proper labeling requirements to meet the needs of the facility and which are consistent with state and federal laws and regulations;
4. Appropriate drug destruction or return of unused drugs, or both, consistent with state and federal laws and regulations.

657—23.8 Reserved.

657—23.9(124,155A) Medication orders. Drugs and prescription devices may be dispensed only upon orders of an authorized prescriber.

23.9(1) *Requirements.* New orders transmitted to the pharmacy for drugs for residents of the facility shall, at a minimum, contain resident name, drug name and strength, directions for use, date of order, and name of prescriber. Orders for Schedule II controlled substances shall comply with the requirements of rule 23.18(124,155A).

23.9(2) *Abbreviations.* Abbreviations or chemical symbols utilized in medication orders shall be only those abbreviations or symbols that are customarily used in the practice of medicine and pharmacy or those on a list of approved abbreviations developed by the appropriate committee or representative of the facility.

23.9(3) *Who may transmit medication orders.* An authorized prescriber or prescriber's agent or any person who is employed by a long-term care facility and who is authorized by the facility's policies and procedures may transmit to the long-term care pharmacy a medication order lawfully ordered by a practitioner authorized to prescribe drugs and devices.

23.9(4) *Influenza and pneumococcal vaccines.* As authorized by federal law, a written or verbal patient-specific medication administration order shall not be required prior to administration to an adult patient of influenza and pneumococcal polysaccharide vaccines pursuant to physician-approved facility policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's record. The facility shall submit to the provider pharmacy a listing of those residents or staff members who have been immunized utilizing vaccine from each vial supplied by the provider pharmacy.

657—23.10(124,155A) Stop orders. The consultant pharmacist, in consultation with the provider pharmacist, the medical director, and the appropriate committee or representative of the facility, shall develop and implement an automatic stop order policy. To ensure that drug orders are not continued inappropriately, drugs not specifically limited when ordered as to duration of therapy or number of doses shall be controlled by the automatic stop order policy in accordance with the status of the patient.

657—23.11(124,155A) Drugs dispensed—general requirements.

23.11(1) *Labeling.* All prescription containers, other than those dispensed pursuant to rule 657—22.1(155A), 23.13(124,155A), or 23.14(124,155A), shall be properly labeled in accordance with 657—subrule 6.10(1).

a. If a label change is required to reflect a change in directions, the pharmacy shall be responsible for affixing the correct label to the container. Long-term care facility personnel shall not be authorized to affix such a label to the drug container.

b. Direction change labels that notify long-term care facility personnel that a change in directions for the drug has taken place may be used and affixed to the container by facility personnel so as not to deface the original label.

23.11(2) *Medication order required.* Dispensing of all drugs to the facility shall be pursuant to a medication order for an individual resident except as provided in rules 23.5(124,155A) and 23.14(124,155A) and in subrule 23.9(4).

23.11(3) *Prescription containers.* All prescription containers, including but not limited to single unit, unit dose, and unit of issue containers utilized for distribution within a long-term care facility, shall meet minimum requirements as established by the United States Pharmacopoeia. When applicable, light-resistant packaging shall be used.

23.11(4) *Floor stock.* Prescription drugs, as defined by Iowa Code section 155A.3(30), 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. A licensed pharmacy under the direct supervision and control of a pharmacist is established in the facility; or

b. The facility and the hospital wherein the licensed pharmacy is located are both licensed under Iowa Code chapter 135B with a single hospital license.

657—23.12 Reserved.

657—23.13(124,155A) Labeling drugs under special circumstances.

23.13(1) *Insulin, ophthalmics, otic preparations, biologicals, and other injectables for individual patients.* These drugs shall be dispensed with a label affixed to the immediate container showing at least the resident's name and location.

23.13(2) *Legend solutions—irrigation and infusion.* Legend irrigation solutions and infusion solutions supplied by a licensed pharmacy may be stored in the locked medication area of a long-term care facility provided that:

a. The facility uses the solution only within the confines of the facility and under the orders of an authorized prescriber;

b. Upon use, the container is identified by resident name and is used exclusively for that resident;

c. The container is dated and initialed upon opening;

d. The solution is stored appropriately after opening according to facility policy.

23.13(3) *Floor-stocked, nonprescription drug containers.* All such nonprescription drugs intended for use within the facility shall be in appropriate containers and adequately labeled to identify, at a minimum, brand name or generic name and manufacturer, strength, lot number, and expiration date. An internal code that centrally references manufacturer and lot number may be utilized.

23.13(4) *Leave meds.* Labeling of prescription drugs for residents on leave from the facility for a period in excess of 24 hours shall comply with 657—subrule 6.10(1). The dispensing pharmacy shall be responsible for packaging and labeling leave meds in compliance with this subrule.

23.13(5) *Discharge meds.* Drugs authorized for a resident being discharged from the facility shall be labeled in compliance with 657—subrule 6.10(1) before the resident removes those drugs from the facility premises. The dispensing pharmacy shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

657—23.14(124,155A) Labeling of biologicals and other injectables supplied to a facility. Labeling of biologicals and other injectables supplied to a facility for a health immunization or ongoing screening program, such as influenza vaccine, tuberculin skin test, or hepatitis-B, and intended for use in the facility, shall include the following information in addition to the manufacturer's label. The pharmacy label shall be affixed so as not to obscure the manufacturer's label.

1. Identification of pharmacy;
2. Name of facility;

3. Name of biological or drug;
4. Route of administration when necessary for clarification;
5. Strength of biological or drug;
6. Auxiliary labels as needed;
7. Date dispensed.

657—23.15(124,155A) Return and reuse of drugs and devices. Pharmacists and pharmacies shall not accept from residents or their agents for reuse or resale any drugs, prescribed drugs, chemicals, poisons or medical devices unless, in the professional judgment of the pharmacist, the integrity of the prescription drug has not in any way been compromised. Under no circumstances shall a pharmacist accept from a patient or patient's agent any controlled substances for return, exchange, or resale except to the same patient. Prescription drugs, excluding controlled substances, dispensed in unit dose, unit of issue, or single unit packaging pursuant to 657—22.1(155A) may, however, be returned and reused as authorized in 657—subrule 22.1(6). No items of a personal contact nature which have been removed from the original package or container after sale shall be accepted for return, exchanged, or resold by any pharmacist.

657—23.16(124,155A) Destruction of outdated and improperly labeled drugs. The consultant pharmacist, in consultation with the provider pharmacist and a facility representative, shall develop and implement written policies and procedures to ensure that all discontinued, outdated, deteriorated, or improperly labeled drugs and all containers with worn, illegible or missing labels are destroyed or disposed of so as to render them unusable. Drugs shall be destroyed by means that will ensure protection against unauthorized possession or use.

657—23.17(124,155A) Accountability of controlled substances.

23.17(1) *Proof of use.* Documentation of use of Schedule II controlled substances shall be upon proof-of-use forms. A committee or representative of the facility may also require that Schedule III, IV, or V controlled substances or any other drugs be accounted for on proof-of-use forms. Proof-of-use forms shall specify at a minimum:

a. Name of drug;
b. Dose;
c. Name of ordering prescriber;
d. Name of resident;
e. Date and time of administration to resident;
f. Identification of individual administering;
g. Documentation of destruction, return to the pharmacy, or other disposition of all unused portions of single doses including the signatures of two individuals, at least one of whom is a licensed health care professional.

23.17(2) *Container requirement.* Any drug required to be counted and accounted for with proof-of-use forms shall be dispensed in a container that allows visual verification of quantity. Containers for solid oral doses must allow visual identification of individual doses and individual accountability.

657—23.18(124,155A) Schedule II orders. This rule shall not apply to Schedule II controlled substances orders in facilities that utilize a floor stock distribution system as provided in subrule 23.11(4). Schedule II controlled substances in all other facilities shall be dispensed only upon receipt of an original written order signed by the prescribing individual practitioner or upon receipt of a facsimile transmission of an original written order signed by the prescribing individual practitioner pursuant to rule 657—21.15(124,155A). In emergency situations as defined in 657—subrule 10.22(1), Schedule II controlled substances may be dispensed in compliance with the requirements of rule 657—10.22(124) or rule 657—21.13(124,155A), as applicable. In all cases, any order for a Schedule II controlled substance shall specify the total quantity authorized by the prescriber.

657—23.19(124,155A) Dispensing Schedule II controlled substances. A pharmacy that dispenses Schedule II controlled substances shall advise facility personnel that federal and state laws and regulations governing such drugs require that accurate records be kept of their administration or their ultimate disposition in compliance with rule 23.17(124,155A). The pharmacy shall further advise facilities that stored Schedule II substances shall be double-locked in accordance with rules of the Iowa department of inspections and appeals. The requirement for double-locking Schedule II controlled substances shall not apply to periods during which drugs are being administered to residents; however, these substances shall be secured during such administration periods.

657—23.20(124,155A) Partial filling of Schedule II controlled substances. A medication order for a Schedule II controlled substance written for a resident in a long-term care facility (LTCF) may be filled in partial quantities to include individual dosage units. The pharmacist shall record on the medication order that the patient is an "LTCF patient." A medication order that is partially filled and does not contain the notation "LTCF patient" shall be deemed to have been filled in violation of the controlled substances Act.

23.20(1) *Partial filling record.* For each partial filling, the dispensing pharmacist shall record on the back of the medication order (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.

23.20(2) *Total dispensed.* The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed.

23.20(3) *Duration.* Schedule II medication orders for residents in a long-term care facility shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the drug.

23.20(4) *Requirements of computerized system.* Information pertaining to current Schedule II medication orders for residents in a long-term care facility may be maintained in a computerized system if this system has the capability to permit:

a. Output (display and printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of resident, address of the long-term care facility, identification of the drug authorized (to include dosage form, strength and quantity), listing of the partial fillings that have been dispensed under each medication order, and the information required in this rule.

b. Immediate (real-time) updating of the medication order record each time a partial filling of the medication order is conducted.

c. Retrieval of partially filled Schedule II medication order information as required in rule 657—21.4(124,155A).

657—23.21(124,155A) Destruction of controlled substances. Controlled substances dispensed to a resident in a long-term care facility and subsequently requiring destruction due to discontinuance of the drug, death of the resident, or other reasons necessitating destruction shall be destroyed by one of the following methods.

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;

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 disposed of;

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

23.21(2) *Destruction or other disposition in the long-term care pharmacy.* 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).

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 155A.2, 155A.13, 155A.15, 155A.21, 155A.27, 155A.28, 155A.33, 155A.35, and 155A.36.

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CHAPTER 24
Reserved

CHAPTER 25
CHILD SUPPORT NONCOMPLIANCE

657—25.1(252J) Definitions. For the purpose of this chapter the following definitions shall apply:

"Act" means Iowa Code chapter 252J.

"Board" means the Iowa board of pharmacy examiners.

"Certificate" means a document known as a certificate of noncompliance which is provided by the child support unit certifying that the named licensee is not in compliance with a support order or with a written agreement for payment of support entered into by the child support unit and the licensee.

"Child support unit" means the child support recovery unit of the Iowa department of human services.

"Denial notice" means a board notification denying an application for the issuance or renewal of a license as required by the Act.

"License" means a license to practice pharmacy, a registration to practice as a pharmacist-intern, a registration to practice as a pharmacy technician, or a registration to possess, prescribe, dispense, administer, distribute, or otherwise handle controlled substances under Iowa Code chapter 124.

"Licensee" means an individual to whom a license has been issued or who is seeking the issuance of a license.

"Revocation or suspension notice" means a board notification suspending a license for an indefinite or specified period of time or a notification revoking a license as required by the Act.

"Withdrawal certificate" means a document known as a withdrawal of a certificate of noncompliance provided by the child support unit certifying that the certificate is withdrawn and that the board may proceed with issuance, reinstatement, or renewal of a license.

657—25.2(252J) Issuance or renewal of license—denial. The board shall deny the issuance or renewal of a license upon the receipt of a certificate from the child support unit. This rule shall apply in addition to the procedures set forth in the Act.

25.2(1) *Service of denial notice.* Notice shall be served upon the licensee by certified mail, return receipt requested; by personal service; or through authorized counsel.

25.2(2) *Effective date of denial.* The effective date of the denial of issuance or renewal of a license, as specified in the notice, shall be 60 days following service of the notice upon the licensee.

25.2(3) *Preparation and service of denial notice.* The executive secretary/director of the board is authorized to prepare and serve the notice upon the licensee.

25.2(4) *Licensee responsible to inform board.* Licensees shall keep the board informed of all court actions and all child support unit actions taken under or in connection with the Act and shall provide the board with copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to the Act, all court orders entered in such actions, and any withdrawal certificates issued by the child support unit.

25.2(5) *Reinstatement following license denial.* All board fees required for application, license renewal, or license reinstatement shall be paid by licensees before a license will be issued, renewed, or reinstated after the board has denied the issuance or renewal of a license pursuant to the Act.

25.2(6) *Effect of filing in district court.* In the event a licensee files a timely district court action following service of a notice, the board shall continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the effective date of the denial of the issuance or renewal of a license, the board shall count the number of days before the action was filed and the number of days after the action was disposed of by the court.

25.2(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board determines appropriate in the circumstances, within ten days of the effective date of the denial of the issuance or renewal of a license and shall similarly notify the licensee if the license is issued or renewed following the board's receipt of a withdrawal certificate.

657—25.3(252J) Suspension or revocation of a license. The board shall suspend or revoke a license upon the receipt of a certificate from the child support unit according to the procedures set forth in the Act. This rule shall apply in addition to the procedures set forth in the Act.

25.3(1) *Service of revocation or suspension notice.* Revocation or suspension notice shall be served upon the licensee by certified mail, return receipt requested; by personal service; or through authorized counsel.

25.3(2) *Effective date of revocation or suspension.* The effective date of the suspension or revocation of a license, as specified in the revocation or suspension notice, shall be 60 days following service of the revocation or suspension notice upon the licensee.

25.3(3) *Preparation and service of revocation or suspension notice.* The executive secretary/director of the board is authorized to prepare and serve the revocation or suspension notice upon the licensee and is directed to notify the licensee that the license will be suspended unless the license is already suspended on other grounds. In the event that the license is on suspension, the executive secretary/director shall notify the licensee of the board's intention to revoke the license.

25.3(4) *Licensee responsible to inform board.* The licensee shall keep the board informed of all court actions and all child support unit action taken under or in connection with the Act and shall provide the board with copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to the Act, all court orders entered in such actions, and any withdrawal certificates issued by the child support unit.

25.3(5) *Reinstatement following license suspension or revocation.* A licensee shall pay all board fees required for license renewal or license reinstatement, and all continuing education requirements shall be met, before a license will be reinstated after the board has suspended a license pursuant to the Act. A licensee whose license to practice pharmacy has been revoked shall complete the examination components as indicated in 657—2.10(155A) and shall pay all required examination fees pursuant to 657—2.2(147). A licensee whose registration to practice as a pharmacist-intern or as a pharmacy technician or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete application and pay all board fees required for new registration.

25.3(6) *Effect of filing in district court.* In the event a licensee files a timely district court action pursuant to the Act and following service of a revocation or suspension notice, the board shall continue with the intended action described in the revocation or suspension notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the effective date of the suspension or revocation, the board shall count the number of days before the action was filed and the number of days after the action was disposed of by the court.

25.3(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board determines appropriate in the circumstances, within ten days of the effective date of the suspension or revocation of a license and shall similarly notify the licensee if a license is reinstated following the board's receipt of a withdrawal certificate.

657—25.4(17A,22,252J) Share information. Notwithstanding any statutory confidentiality provision, the board may share information with the child support unit through manual or automated means for the sole purpose of identifying applicants or licensees subject to enforcement under the Act.

These rules are intended to implement Iowa Code chapter 252J.

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CHAPTER 26
PETITIONS FOR RULE MAKING

657—26.1(17A) Petition for rule making. Any person, association, agency, or political subdivision may file a petition for rule making with the board at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. A petition is deemed filed when received by that office. The board shall provide the petitioner with a file-stamped copy of the petition if the petitioner provides the board an extra copy for this purpose. The petition must be typewritten, machine printed, or legibly handwritten in ink and must substantially conform to the following form:

BOARD OF PHARMACY EXAMINERS

Petition by (Name of Petitioner) for the (adoption, amendment, or repeal) of rules relating to (state subject matter).	}	PETITION FOR RULE MAKING

The petition shall include the following information:

1. A statement of the specific rule-making action sought by the petitioner including the text or a summary of the contents of the proposed rule or amendment to a rule and, if it is a petition to amend or repeal a rule, a citation and the relevant language to the particular portion or portions of the rule proposed to be amended or repealed.
2. A citation to any law deemed relevant to the board's authority to take the action urged or to the desirability of that action.
3. A brief summary of petitioner's arguments in support of the action urged in the petition.
4. A brief summary of any data supporting the action urged in the petition.
5. The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by or interested in, the proposed action which is the subject of the petition.
6. Any request by petitioner for a meeting provided for by rule 26.4(17A).
7. Original signature of petitioner and date signed.

657—26.2(17A) Briefs. The petitioner may attach a brief to the petition in support of the action urged in the petition. The board may request a brief from the petitioner or from any other person concerning the substance of the petition.

657—26.3(17A) Inquiries. Inquiries concerning the status of a petition for rule making may be made to Executive Secretary/Director, Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, or via electronic mail to lloyd.jessen@ibpe.state.ia.us.

657—26.4(17A) Board consideration.

26.4(1) *Initial activities.* Within 14 days after the filing of a petition, the board shall submit a copy of the petition and any accompanying brief to the administrative rules coordinator and to the administrative rules review committee. Upon request by petitioner in the petition, the board shall schedule a brief and informal meeting between the petitioner and the board, a member of the board, or a member of the staff of the board to discuss the petition. The board may request that the petitioner submit additional information or argument concerning the petition. The board may also solicit comments from any person on the substance of the petition. Any person may submit to the board comments on the substance of the petition.

26.4(2) *Decision issued.* Within 60 days after the filing of the petition, or within any longer period agreed to by the petitioner, the board shall, in writing, deny the petition, and notify petitioner of its action and the specific grounds for the denial, or grant the petition and notify petitioner that it has instituted rule-making proceedings on the subject of the petition. Petitioner shall be deemed notified of the denial or grant of the petition on the date when the board mails or delivers the required notification to petitioner.

26.4(3) *Denial for nonconformity.* Denial of a petition because it does not substantially conform to the required form does not preclude the filing of a new petition on the same subject that seeks to eliminate the grounds for the board's rejection of the original petition.

These rules are intended to implement Iowa Code section 17A.7.

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CHAPTER 27
DECLARATORY ORDERS

657—27.1(17A) Petition for declaratory order. Any person may file a petition with the board of pharmacy examiners, hereinafter referred to as "the board," for a declaratory order as to the applicability to specified circumstances of a statute, rule, or order within the primary jurisdiction of the Iowa Board of Pharmacy Examiners at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. A petition is deemed filed when it is received by that office. The board shall provide the petitioner with a file-stamped copy of the petition if the petitioner provides the board an extra copy for this purpose. The petition shall be typewritten or legibly handwritten in ink and shall substantially conform to the following form:

IOWA BOARD OF PHARMACY EXAMINERS

Petition by (Name of Petitioner)for a Declaratory Order on(Cite provisions of law involved).	PETITION FOR DECLARATORY ORDER

The petition shall provide the following information:

1. A clear and concise statement of all relevant facts on which the order is requested.
2. A citation and the relevant language of the specific statutes, rules, policies, decisions, or orders, whose applicability is questioned, and any other relevant law.
3. The questions petitioner wants answered, stated clearly and concisely.
4. The answers to the questions desired by the petitioner and a summary of the reasons urged by the petitioner in support of those answers.
5. The reasons for requesting the declaratory order and disclosure of the petitioner's interest in the outcome.
6. A statement indicating whether the petitioner is currently a party to another proceeding involving the questions at issue and whether, to the petitioner's knowledge, those questions have been decided by, are pending determination by, or are under investigation by, any governmental entity.
7. The names and addresses of other persons, or a description of any class of persons, known by petitioner to be affected by, or interested in, the questions presented in the petition.
8. Any request by petitioner for a meeting provided for by 657—27.7(17A).

The petition shall be dated and signed by the petitioner or the petitioner's representative. It shall also include the name, mailing address, and telephone number of the petitioner and petitioner's representative and a statement indicating the person to whom communications concerning the petition should be directed.

657—27.2(17A) Notice of petition. Within 15 days after receipt of a petition for a declaratory order, the board shall give notice of the petition to all persons not served by the petitioner pursuant to 657—27.6(17A) to whom notice is required by any provision of law. The board may also give notice to any other persons.

657—27.3(17A) Intervention.

27.3(1) Persons who qualify under any applicable provision of law as an intervenor and who file a petition for intervention within 20 days of the filing of a petition for declaratory order shall be allowed to intervene in a proceeding for a declaratory order.

27.3(2) Any person who files a petition for intervention at any time prior to the issuance of an order may be allowed to intervene in a proceeding for a declaratory order at the discretion of the board.

27.3(3) A petition for intervention shall be filed at the board office at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Such a petition is deemed filed when it is received by that office. The board will provide the petitioner with a file-stamped copy of the petition for intervention if the

petitioner provides an extra copy for this purpose. A petition for intervention shall be typewritten or legibly handwritten in ink and shall substantially conform to the following form:

IOWA BOARD OF PHARMACY EXAMINERS

Petition by (Name of Original Petitioner) for a Declaratory Order on (Cite provisions of law cited in original petition).	}	PETITION FOR INTERVENTION

The petition for intervention shall provide the following information:

1. Facts supporting the intervenor's standing and qualifications for intervention.
2. The answers urged by the intervenor to the question or questions presented and a summary of the reasons urged in support of those answers.
3. Reasons for requesting intervention and disclosure of the intervenor's interest in the outcome.
4. A statement indicating whether the intervenor is currently a party to any proceeding involving the questions at issue and whether, to the intervenor's knowledge, those questions have been decided by, are pending determination by, or are under investigation by, any governmental entity.
5. The names and addresses of any additional persons, or a description of any additional class of persons, known by the intervenor to be affected by, or interested in, the questions presented.
6. Whether the intervenor consents to be bound by the determination of the matters presented in the declaratory order proceeding.

The petition shall be dated and signed by the intervenor or the intervenor's representative. It shall also include the name, mailing address, and telephone number of the intervenor and intervenor's representative, and a statement indicating the person to whom communications should be directed.

657—27.4(17A) Briefs. The petitioner or any intervenor may file a brief in support of the position urged. The board may request a brief from the petitioner, any intervenor, or any other person concerning the questions raised.

657—27.5(17A) Inquiries. Inquiries concerning the status of a declaratory order proceeding may be made to the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

657—27.6(17A) Service and filing of petitions and other papers.

27.6(1) *When service required.* Except where otherwise provided by law, every petition for declaratory order, petition for intervention, brief, or other paper filed in a proceeding for a declaratory order shall be served upon each of the parties of record to the proceeding, and on all other persons identified in the petition for declaratory order or petition for intervention as affected by or interested in the questions presented, simultaneously with their filing. The party filing a document is responsible for service on all parties and other affected or interested persons.

27.6(2) *Filing—when required.* All petitions for declaratory orders, petitions for intervention, briefs, or other papers in a proceeding for a declaratory order shall be filed with the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. All petitions, briefs, or other papers that are required to be served upon a party shall be filed simultaneously with the board.

27.6(3) *Method of service, time of filing, and proof of mailing.* Method of service, time of filing, and proof of mailing shall be as provided by 657—35.11(17A,272C).

657—27.7(17A) Consideration. Upon request by petitioner, the board shall schedule a brief and informal meeting between the original petitioner, all intervenors, and the board, a member of the board, or a member of the staff of the board, to discuss the questions raised. The board may solicit comments from any person on the questions raised. Also, comments on the questions raised may be submitted to the board by any person.

657—27.8(17A) Action on petition.

27.8(1) Within the time allowed by 1998 Iowa Acts, chapter 1202, section 13(5), after receipt of a petition for a declaratory order, the executive secretary/director or designee shall take action on the petition as required by 1998 Iowa Acts, chapter 1202, section 13(5).

27.8(2) The date of issuance of an order or of a refusal to issue an order is as defined in 657—35.2(17A,272C).

657—27.9(17A) Refusal to issue order.

27.9(1) The board shall not issue a declaratory order where prohibited by 1998 Iowa Acts, chapter 1202, section 13(1), and may refuse to issue a declaratory order on some or all questions raised for the following reasons:

1. The petition does not substantially comply with the required form.
2. The petition does not contain facts sufficient to demonstrate that the petitioner will be aggrieved or adversely affected by the failure of the board to issue an order.
3. The board does not have jurisdiction over the questions presented in the petition.
4. The questions presented by the petition are also presented in a current rule making, contested case, or other board or judicial proceeding, that may definitively resolve them.
5. The questions presented by the petition would more properly be resolved in a different type of proceeding or by another body with jurisdiction over the matter.
6. The facts or questions presented in the petition are unclear, overbroad, insufficient, or otherwise inappropriate as a basis upon which to issue an order.
7. There is no need to issue an order because the questions raised in the petition have been settled due to a change in circumstances.
8. The petition is not based upon facts calculated to aid in the planning of future conduct but is, instead, based solely upon prior conduct in an effort to establish the effect of that conduct or to challenge a board decision already made.
9. The petition requests a declaratory order that would necessarily determine the legal rights, duties, or responsibilities of other persons who have not joined in the petition, intervened separately, or filed a similar petition and whose position on the questions presented may fairly be presumed to be adverse to that of petitioner.
10. The petitioner requests the board to determine whether a statute is unconstitutional on its face.

27.9(2) A refusal to issue a declaratory order shall indicate the specific grounds for the refusal and constitutes final board action on the petition.

27.9(3) Refusal to issue a declaratory order pursuant to this provision does not preclude the filing of a new petition that seeks to eliminate the grounds for the refusal to issue an order.

657—27.10(17A) Contents of declaratory order—effective date. In addition to the order itself, a declaratory order shall contain the date of its issuance, the name of petitioner and all intervenors, the specific statutes, rules, policies, decisions, or orders involved, the particular facts upon which it is based, and the reasons for its conclusion. A declaratory order is effective on the date of issuance.

657—27.11(17A) Copies of orders. A copy of all orders issued in response to a petition for a declaratory order shall be mailed promptly to the original petitioner and all intervenors.

657—27.12(17A) Effect of a declaratory order. A declaratory order has the same status and binding effect as a final order issued in a contested case proceeding. It is binding on the board, the petitioner, and any intervenors and is applicable only in circumstances where the relevant facts and the law involved are indistinguishable from those on which the order was based. As to all other persons, a declaratory order serves only as precedent and is not binding on the board. The issuance of a declaratory order constitutes final board action on the petition.

These rules are intended to implement Iowa Code section 17A.9 as amended by 1998 Iowa Acts, chapter 1202, section 13.

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CHAPTER 28
AGENCY PROCEDURE FOR RULE MAKING

657—28.1(17A) Applicability. Except to the extent otherwise expressly provided by statute, all rules adopted by the board of pharmacy examiners, hereinafter referred to as "board," are subject to the provisions of Iowa Code chapter 17A, the Iowa administrative procedure Act, and the provisions of this chapter.

657—28.2(17A) Advice on possible rules before notice of proposed rule adoption. In addition to seeking information by other methods, the board may, before publication of a Notice of Intended Action under Iowa Code section 17A.4(1)*"a,"* solicit comments from the public on a subject matter of possible rule making by the board by causing notice to be published in the Iowa Administrative Bulletin of the subject matter and indicating where, when, and how persons may comment.

657—28.3(17A) Public rule-making docket.

28.3(1) *Docket maintained.* The board shall maintain a current public rule-making docket.

28.3(2) *Anticipated rule making.* The rule-making docket shall list each anticipated rule-making proceeding. A rule-making proceeding is deemed "anticipated" from the time a draft of proposed rules is distributed for internal discussion within the board. For each anticipated rule-making proceeding the docket shall contain a listing of the precise subject matter which may be submitted for consideration by the board for subsequent proposal under the provisions of Iowa Code section 17A.4(1)*"a,"* the name and address of board personnel with whom persons may communicate with respect to the matter, and an indication of the present status within the board of that possible rule. The board may also include in the docket other subjects upon which public comment is desired.

28.3(3) *Pending rule-making proceedings.* The rule-making docket shall list each pending rule-making proceeding. A rule-making proceeding is pending from the time it is commenced, by publication in the Iowa Administrative Bulletin of a Notice of Intended Action pursuant to Iowa Code section 17A.4(1)*"a,"* to the time it is terminated, by publication of a Notice of Termination in the Iowa Administrative Bulletin, or the rule becoming effective. For each rule-making proceeding, the docket shall indicate:

a. The subject matter of the proposed rule;

b. A citation to all published notices relating to the proceeding;

c. Where written submissions on the proposed rule may be inspected;

d. The time during which written submissions may be made;

e. The names of persons who have made written requests for an opportunity to make oral presentations on the proposed rule, where those requests may be inspected, and where and when oral presentations may be made;

f. Whether a written request for the issuance of a regulatory analysis or a concise statement of reasons has been filed, whether such an analysis or statement or a fiscal impact statement has been issued, and where any such written request, analysis, or statement may be inspected;

g. The current status of the proposed rule and any board determinations with respect thereto;

h. Any known timetable for board decisions or other action in the proceeding;

i. The date of the rule's adoption;

j. The date of the rule's filing, indexing, and publication;

k. The date on which the rule will become effective; and

l. Where the rule-making record may be inspected.

657—28.4(17A) Notice of proposed rule making.

28.4(1) *Contents.* At least 35 days before the adoption of a rule the board shall cause Notice of Intended Action to be published in the Iowa Administrative Bulletin. The Notice of Intended Action shall include:

a. A brief explanation of the purpose of the proposed rule;

b. The specific legal authority for the proposed rule;

c. Except to the extent impracticable, the text of the proposed rule;

d. Where, when, and how persons may present their views on the proposed rule; and

e. Where, when, and how persons may demand an oral proceeding on the proposed rule if the notice does not already provide for one.

Where inclusion of the complete text of a proposed rule in the Notice of Intended Action is impracticable, the board shall include in the notice a statement fully describing the specific subject matter of the omitted portion of the text of the proposed rule, the specific issues to be addressed by that omitted text of the proposed rule, and the range of possible choices being considered by the board for the resolution of each of those issues.

28.4(2) *Incorporation by reference.* A proposed rule may incorporate other materials by reference only if it complies with all of the requirements applicable to the incorporation by reference of other materials in an adopted rule that are contained in subrule 28.12(2) of this chapter.

28.4(3) *Copies of notices.* Persons desiring to receive copies of future Notices of Intended Action by subscription shall file with the board a written request indicating the name and address to which such notices should be sent. Within seven days after submission of a Notice of Intended Action to the administrative rules coordinator for publication in the Iowa Administrative Bulletin, the board shall mail or electronically transmit a copy of that notice to subscribers who have filed a written request for either mailing or electronic transmittal with the board for Notices of Intended Action. The written request shall be accompanied by payment of the subscription price which may cover the full cost of the subscription service, including its administrative overhead and the cost of copying and mailing the Notices of Intended Action for a period of one year.

657—28.5(17A) Public participation.

28.5(1) *Written comments.* For at least 20 days after publication of the Notice of Intended Action, persons may submit argument, data, and views, in writing, on the proposed rule. Such written submissions shall identify the proposed rule to which they relate and shall be submitted to the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, or the person designated in the Notice of Intended Action.

28.5(2) *Oral proceedings.* The board may, at any time, schedule an oral proceeding on a proposed rule. The board shall schedule an oral proceeding on a proposed rule if, within 20 days after the published Notice of Intended Action, a written request for an opportunity to make oral presentations is submitted to the board by the administrative rules review committee, a governmental subdivision, an agency, an association having not less than 25 members, or at least 25 persons. That request shall also contain the following additional information:

a. A request by one or more individual persons shall be signed by each of them and include the address and telephone number of each of them.

b. A request by an association shall be signed by an officer or designee of the association and shall contain a statement that the association has at least 25 members and the address and telephone number of the person signing that request.

c. A request by an agency or governmental subdivision shall be signed by an official having authority to act on behalf of the entity and shall contain the address and telephone number of the person signing that request.

28.5(3) *Conduct of oral proceedings.*

a. Applicability. This subrule applies only to those oral rule-making proceedings in which an opportunity to make oral presentations is authorized or required by Iowa Code section 17A.4(1)*"b"* as amended by 1998 Iowa Acts, chapter 1202, section 8, or subrule 28.5(2).

b. Scheduling and notice. An oral proceeding on a proposed rule may be held in one or more locations and shall not be held earlier than 20 days after notice of its location and time is published in the Iowa Administrative Bulletin. That notice shall also identify the proposed rule by ARC number and citation to the Iowa Administrative Bulletin.

c. Presiding officer. The board, a member of the board, or another person designated by the board who will be familiar with the substance of the proposed rule, shall preside at the oral proceeding on a proposed rule. If the board does not preside, the presiding officer shall prepare a memorandum for consideration by the board summarizing the contents of the presentations made at the oral proceeding unless the board determines that such a memorandum is unnecessary because the board will personally listen to or read the entire transcript of the oral proceeding.

d. Conduct of proceeding. At an oral proceeding on a proposed rule, persons may make oral statements and make documentary and physical submissions, which may include data, views, comments or arguments concerning the proposed rule. Persons wishing to make oral presentations at such a proceeding are encouraged to notify the board at least one business day prior to the proceeding and indicate the general subject of their presentations. At the proceeding, those who participate shall indicate their names and addresses, identify any persons or organizations they may represent, and provide any other information relating to their participation deemed appropriate by the presiding officer. Oral proceedings shall be open to the public and shall be recorded by stenographic or electronic means.

(1) At the beginning of the oral proceeding, the presiding officer shall give a brief synopsis of the proposed rule, a statement of the statutory authority for the proposed rule, and the reasons for the board decision to propose the rule. The presiding officer may place time limitations on individual oral presentations when necessary to ensure the orderly and expeditious conduct of the oral proceeding. To encourage joint oral presentations and to avoid repetition, additional time may be provided for persons whose presentations represent the views of other individuals as well as their own views.

(2) Persons making oral presentations are encouraged to avoid restating matters which have already been submitted in writing.

(3) To facilitate the exchange of information, the presiding officer may, where time permits, open the floor to questions or general discussion.

(4) The presiding officer shall have the authority to take any reasonable action necessary for the orderly conduct of the meeting.

(5) Physical and documentary submissions presented by participants in the oral proceeding shall be submitted to the presiding officer. Such submissions become the property of the board.

(6) The oral proceeding may be continued by the presiding officer to a later time without notice other than by announcement at the hearing.

(7) Participants in an oral proceeding shall not be required to take an oath or to submit to cross-examination. However, the presiding officer in an oral proceeding may question participants and permit the questioning of participants by other participants about any matter relating to that rule-making proceeding, including any prior written submissions made by those participants in that proceeding; but no participant shall be required to answer any question.

(8) The presiding officer in an oral proceeding may permit rebuttal statements and request the filing of written statements subsequent to the adjournment of the oral presentations.

28.5(4) *Additional information.* In addition to receiving written comments and oral presentations on a proposed rule according to the provisions of this rule, the board may obtain information concerning a proposed rule through any other lawful means deemed appropriate under the circumstances.

28.5(5) *Accessibility.* The board shall schedule oral proceedings in rooms accessible to and functional for persons with physical disabilities. Persons who have special requirements should contact the board of pharmacy examiners, telephone (515)281-5944, in advance to arrange access or other needed services.

657—28.6(17A) Regulatory analysis.

28.6(1) *Definition of small business.* A "small business" is defined in 1998 Iowa Acts, chapter 1202, section 10(7).

28.6(2) *Mailing list.* Small businesses or organizations of small businesses may be registered on the board's small business impact list by making a written application addressed to the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The application for registration shall state:

a. The name of the small business or organization of small businesses;

b. Its address;

c. The name of a person authorized to transact business for the applicant;

d. A description of the applicant's business or organization. An organization representing 25 or more persons who qualify as a small business shall indicate that fact.

e. Whether the registrant desires copies of Notices of Intended Action at cost, or desires advance notice of the subject of all or some specific category of proposed rule making affecting small business.

The board may at any time request additional information from the applicant to determine whether the applicant is qualified as a small business or as an organization of 25 or more small businesses. The board may periodically send a letter to each registered small business or organization of small businesses asking whether that business or organization wishes to remain on the registration list. The name of a small business or organization of small businesses will be removed from the list if a negative response is received or if no response is received within 30 days after the letter is sent.

28.6(3) *Time of mailing.* Within seven days after submission of a Notice of Intended Action to the administrative rules coordinator for publication in the Iowa Administrative Bulletin, the board shall mail to all registered small businesses or organizations of small businesses, in accordance with their request, either a copy of the Notice of Intended Action or notice of the subject of that proposed rule making. In the case of a rule that may have an impact on small business adopted in reliance upon Iowa Code section 17A.4(2), the board shall mail notice of the adopted rule to registered businesses or organizations prior to the time the adopted rule is published in the Iowa Administrative Bulletin.

28.6(4) *Qualified requesters for regulatory analysis— economic impact.* The board shall issue a regulatory analysis of a proposed rule that conforms to the requirements of 1998 Iowa Acts, chapter 1202, section 10(2a), after a proper request from:

a. The administrative rules coordinator or

b. The administrative rules review committee.

28.6(5) *Qualified requesters for regulatory analysis— business impact.* The board shall issue a regulatory analysis of a proposed rule that conforms to the requirements of 1998 Iowa Acts, chapter 1202, section 10(2b), after a proper request from:

a. The administrative rules review committee;

b. The administrative rules coordinator;

c. At least 25 or more persons who sign the request provided that each represents a different small business;

d. An organization representing at least 25 small businesses. That organization shall list the name, address, and telephone number of not less than 25 small businesses it represents.

28.6(6) *Time period for analysis.* Upon receipt of a timely request for a regulatory analysis the board shall adhere to the time lines described in 1998 Iowa Acts, chapter 1202, section 10(4).

28.6(7) *Contents of request.* A request for a regulatory analysis is made when it is mailed or delivered to the board. The request shall be in writing and satisfy the requirements of 1998 Iowa Acts, chapter 1202, section 10(1).

28.6(8) *Contents of concise summary.* The contents of the concise summary shall conform to the requirements of 1998 Iowa Acts, chapter 1202, section 10(4,5).

28.6(9) *Publication of a concise summary.* The board shall make available, to the maximum extent feasible, copies of the published summary in conformance with 1998 Iowa Acts, chapter 1202, section 10(5).

28.6(10) *Regulatory analysis contents—rules review committee or rules coordinator.* When a regulatory analysis is issued in response to a written request from the administrative rules review committee or the administrative rules coordinator, the regulatory analysis shall conform to the requirements of 1998 Iowa Acts, chapter 1202, section 10(2a), unless a written request expressly waives one or more of the items listed in the section.

28.6(11) *Regulatory analysis contents—substantial impact on small business.* When a regulatory analysis is issued in response to a written request from the administrative rules review committee, the administrative rules coordinator, at least 25 persons signing that request who each qualify as a small

business, or by an organization representing at least 25 small businesses, the regulatory analysis shall conform to the requirements of 1998 Iowa Acts, chapter 1202, section 10(2b).

657—28.7(17A,25B) Fiscal impact statement.

28.7(1) A proposed rule that mandates additional combined expenditures exceeding $100,000 by all affected political subdivisions or agencies and entities which contract with political subdivisions to provide services shall be accompanied by a fiscal impact statement outlining the costs associated with the rule. A fiscal impact statement shall satisfy the requirements of Iowa Code section 25B.6.

28.7(2) If the board determines at the time it adopts a rule that the fiscal impact statement upon which the rule is based contains errors, the board shall, at the same time, issue a corrected fiscal impact statement and publish the corrected fiscal impact statement in the Iowa Administrative Bulletin.

657—28.8(17A) Time and manner of rule adoption.

28.8(1) *Time of adoption.* The board shall not adopt a rule until the period for making written submissions and oral presentations has expired. Within 180 days after the later of the publication of the Notice of Intended Action, or the end of oral proceedings thereon, the board shall adopt a rule pursuant to the rule-making proceeding or terminate the proceeding by publication of a notice to that effect in the Iowa Administrative Bulletin.

28.8(2) *Consideration of public comment.* Before the adoption of a rule, the board shall consider fully all of the written submissions and oral submissions received in that rule-making proceeding, or any memorandum summarizing such oral submissions, and any regulatory analysis or fiscal impact statement issued in that rule-making proceeding.

28.8(3) *Reliance on board expertise.* Except as otherwise provided by law, the board may use its own experience, technical competence, specialized knowledge, and judgment in the adoption of a rule.

657—28.9(17A) Variance between adopted rule and published notice of proposed rule adoption.

28.9(1) The board shall not adopt a rule that differs from the rule proposed in the Notice of Intended Action on which the rule is based unless:

a. The differences are within the scope of the subject matter announced in the Notice of Intended Action and are in character with the issues raised in that notice; and

b. The differences are a logical outgrowth of the contents of that Notice of Intended Action and the comments submitted in response thereto; and

c. The Notice of Intended Action provided fair warning that the outcome of that rule-making proceeding could be the rule in question.

28.9(2) In determining whether the Notice of Intended Action provided fair warning that the outcome of that rule-making proceeding could be the rule in question, the board shall consider the following factors:

a. The extent to which persons who will be affected by the rule should have understood that the rule-making proceeding on which it is based could affect their interests;

b. The extent to which the subject matter of the rule or the issues determined by the rule are different from the subject matter or issues contained in the Notice of Intended Action; and

c. The extent to which the effects of the rule differ from the effects of the proposed rule contained in the Notice of Intended Action.

28.9(3) The board shall commence a rule-making proceeding within 60 days of its receipt of a petition for rule making seeking the amendment or repeal of a rule that differs from the proposed rule contained in the Notice of Intended Action upon which the rule is based, unless the board finds that the differences between the adopted rule and the proposed rule are so insubstantial as to make such a rule-making proceeding wholly unnecessary. A copy of any such finding and the petition to which it responds shall be sent to petitioner, the administrative rules coordinator, and the administrative rules review committee, within three days of its issuance.

28.9(4) Concurrent rule-making proceedings. Nothing in this rule disturbs the discretion of the board to initiate, concurrently, several different rule-making proceedings on the same subject with several different published Notices of Intended Action.

657—28.10(17A) Exemptions from public rule-making procedures.

28.10(1) *Omission of notice and comment* **.** To the extent the board for good cause finds that public notice and participation are unnecessary, impracticable, or contrary to the public interest in the process of adopting a particular rule, the board may adopt that rule without publishing advance Notice of Intended Action in the Iowa Administrative Bulletin and without providing for written or oral public submissions prior to its adoption. The board shall incorporate the required finding and a brief statement of its supporting reasons in each rule adopted in reliance upon this subrule.

28.10(2) *Categories exempt.* The following narrowly tailored categories of rules are exempted from the usual public notice and participation requirements because those requirements are unnecessary, impracticable, or contrary to the public interest with respect to each and every member of the defined class:

a. Temporary designation of controlled substances consistent with federal Drug Enforcement Administration action to add a substance to a drug schedule or to change the schedule within which a substance is controlled under the Controlled Substances Act.

b. Amend references to the Iowa Code, the Iowa Administrative Code, or the Code of Federal Regulations where such references change or are otherwise incorrect.

c. Change the name, address, or telephone number of the board of pharmacy examiners or an authorized contact person.

28.10(3) *Public proceedings on rules adopted without them.* The board may, at any time, commence a standard rule-making proceeding for the adoption of a rule that is identical or similar to a rule it adopts in reliance upon subrule 28.10(1). Upon written petition by a governmental subdivision, the administrative rules review committee, an agency, the administrative rules coordinator, an association having not less than 25 members, or at least 25 persons, the board shall commence a standard rule-making proceeding for any rule specified in the petition that was adopted in reliance upon subrule 28.10(1). Such a petition shall be filed within one year of the publication of the specified rule in the Iowa Administrative Bulletin as an adopted rule. The rule-making proceeding on that rule shall be commenced within 60 days of the receipt of such a petition. After a standard rule-making proceeding commenced pursuant to this subrule, the board may either readopt the rule it adopted without benefit of all usual procedures on the basis of subrule 28.10(1), or may take any other lawful action, including the amendment or repeal of the rule in question, with whatever further proceedings are appropriate.

657—28.11(17A) Concise statement of reasons.

28.11(1) *General.* When requested by a person, either prior to the adoption of a rule or within 30 days after its publication in the Iowa Administrative Bulletin as an adopted rule, the board shall issue a concise statement of reasons for the rule. Requests for such a statement shall be in writing and be delivered to the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The request shall indicate whether the statement is sought for all or only a specified part of the rule. Requests will be considered made on the date received.

28.11(2) *Contents.* The concise statement of reasons shall contain:

a. The reasons for adopting the rule;

b. An indication of any change between the text of the proposed rule contained in the published Notice of Intended Action and the text of the rule as finally adopted, with the reasons for any such change;

c. The principal reasons urged in the rule-making proceeding for and against the rule, and the board's reasons for overruling the arguments made against the rule.

28.11(3) *Time of issuance.* After a proper request, the board shall issue a concise statement of reasons by the later of the time the rule is adopted or 35 days after receipt of the request.

657—28.12(17A) Contents, style, and form of rule.

28.12(1) *Contents.* Each rule adopted by the board shall contain the text of the rule and, in addition:

a. The date the board adopted the rule;

b. A brief explanation of the principal reasons for the rule-making action if such reasons are required by 1998 Iowa Acts, chapter 1202, section 8, or the board in its discretion decides to include such reasons;

c. A reference to all rules repealed, amended, or suspended by the rule;

d. A reference to the specific statutory or other authority authorizing adoption of the rule;

e. Any findings required by any provision of law as a prerequisite to adoption or effectiveness of the rule;

f. A brief explanation of the principal reasons for the failure to provide for waivers to the rule if no waiver provision is included and a brief explanation of any waiver or special exceptions provided in the rule if such reasons are required by 1998 Iowa Acts, chapter 1202, section 8, or the board in its discretion decides to include such reasons; and

g. The effective date of the rule.

28.12(2) *Incorporation by reference.* The board may incorporate by reference in a proposed or adopted rule, and without causing publication of the incorporated matter in full, all or any part of a code, standard, rule, or other matter if the board finds that the incorporation of its text in the board proposed or adopted rule would be unduly cumbersome, expensive, or otherwise inexpedient. The reference in the board proposed or adopted rule shall fully and precisely identify the incorporated matter by location, title, citation, date, and edition, if any; shall briefly indicate the precise subject and the general contents of the incorporated matter; and shall state that the proposed or adopted rule does not include any later amendments or editions of the incorporated matter. The board may incorporate such matter by reference in a proposed or adopted rule only if the board makes copies of it readily available to the public. The rule shall state how and where copies of the incorporated matter may be obtained at cost from the board, and how and where copies may be obtained from the agency of the United States, this state, another state, or the organization, association, or persons, originally issuing that matter. The board shall retain permanently a copy of any materials incorporated by reference in a rule of the board.

If the board adopts standards by reference to another publication, it shall provide a copy of the publication containing the standards to the administrative rules coordinator for deposit in the state law library and may make the standards available electronically.

28.12(3) *References to materials not published in full.* When the administrative code editor decides to omit the full text of a proposed or adopted rule because publication of the full text would be unduly cumbersome, expensive, or otherwise inexpedient, the board shall prepare and submit to the administrative code editor for inclusion in the Iowa Administrative Bulletin and Iowa Administrative Code a summary statement describing the specific subject matter of the omitted material. This summary statement shall include the title and a brief description sufficient to inform the public of the specific nature and subject matter of the proposed or adopted rules and of significant issues involved in these rules. The summary statement shall also describe how a copy of the full text of the proposed or adopted rule, including any unpublished matter and any matter incorporated by reference, may be obtained from the board. The board will provide a copy of that full text, at actual cost upon request, and shall make copies of the full text available for review at the state law library and may make the standards available electronically.

At the request of the administrative code editor, the board shall provide a proposed statement explaining why publication of the full text would be unduly cumbersome, expensive, or otherwise inexpedient.

28.12(4) *Style and form.* In preparing its rules, the board shall follow the uniform numbering system, form, and style prescribed by the administrative rules coordinator.

657—28.13(17A) Board rule-making record.

28.13(1) *Requirement.* The board shall maintain an official rule-making record for each rule it proposes by publication in the Iowa Administrative Bulletin of a Notice of Intended Action or adopts. The rule-making record and materials incorporated by reference shall be available for public inspection.

28.13(2) *Contents.* The board rule-making record shall contain:

a. Copies of all publications in the Iowa Administrative Bulletin with respect to the rule or the proceeding upon which the rule is based and any file-stamped copies of board submissions to the administrative rules coordinator concerning that rule or the proceeding upon which it is based;

b. Copies of any portions of the board's public rule-making docket containing entries relating to the rule or the proceeding upon which the rule is based;

c. All written petitions, requests, and submissions received by the board, and all other written materials of a factual nature as distinguished from opinion that are relevant to the merits of the rule and that were created or compiled by the board and considered by the board, in connection with the formulation, proposal, or adoption of the rule or the proceeding upon which the rule is based, except to the extent the board is authorized by law to keep them confidential; provided, however, that when any such materials are deleted because they are authorized by law to be kept confidential, the board shall identify in the record the particular materials deleted and state the reasons for that deletion;

d. Any official transcript of oral presentations made in the proceeding upon which the rule is based or, if not transcribed, the stenographic record or electronic recording of those presentations, and any memorandum prepared by a presiding officer summarizing the contents of those presentations;

e. A copy of any regulatory analysis or fiscal impact statement prepared for the proceeding upon which the rule is based;

f. A copy of the rule and any concise statement of reasons prepared for that rule;

g. All petitions for amendment of, or repeal or suspension of, the rule;

h. A copy of any objection to the issuance of that rule without public notice and participation that was filed pursuant to Iowa Code section 17A.4(2) by the administrative rules review committee, the governor, or the attorney general;

i. A copy of any objection to the rule filed by the administrative rules review committee, the governor, or the attorney general pursuant to Iowa Code section 17A.4(4), and any board response to that objection;

j. A copy of any significant written criticism of the rule, including a summary of any petitions for waiver of the rule; and

k. A copy of any executive order concerning the rule.

28.13(3) *Effect of record.* Except as otherwise required by a provision of law, the board rule-making record required by this rule need not constitute the exclusive basis for board action on that rule.

28.13(4) *Maintenance of record.* The board shall maintain the rule-making record for a period of not less than five years from the later of the date the rule to which it pertains became effective or the date of the Notice of Intended Action. The board shall maintain a record of significant written criticism as described in 28.13(2), paragraphs *"g," "h," "i,"* or *"j,"* for a period of not less than five years from the date of the written criticism.

657—28.14(17A) Filing of rules. The board shall file each rule it adopts in the office of the administrative rules coordinator. The filing shall be executed as soon after adoption of the rule as is practicable. At the time of filing, each rule shall have attached to it any fiscal impact statement and any concise statement of reasons that was issued with respect to that rule. If a fiscal impact statement or statement of reasons for that rule was not issued until a time subsequent to the filing of that rule, the note or statement shall be attached to the filed rule within five working days after the note or statement is issued. In filing a rule, the board shall use the standard form prescribed by the administrative rules coordinator.

657—28.15(17A) Effectiveness of rules prior to publication.

28.15(1) *Grounds.* The board may make a rule effective after its filing at any stated time prior to 35 days after its indexing and publication in the Iowa Administrative Bulletin if it finds that a statute so provides, the rule confers a benefit or removes a restriction on some segment of the public, or that the effective date of the rule is necessary to avoid imminent peril to the public health, safety, or welfare. The board shall incorporate the required finding and a brief statement of its supporting reasons in each rule adopted in reliance upon this subrule.

28.15(2) *Special notice.* When the board makes a rule effective prior to its indexing and publication in reliance upon the provisions of Iowa Code section 17A.5(2)*"b"*(3), the board shall employ all reasonable efforts to make its contents known to the persons who may be affected by that rule prior to the rule's indexing and publication. The term "all reasonable efforts" requires the board to employ the most effective and prompt means of notice rationally calculated to inform potentially affected parties of the effectiveness of the rule that is justified and practical under the circumstances considering the various alternatives available for this purpose, the comparative costs to the board of utilizing each of those alternatives, and the harm suffered by affected persons from any lack of notice concerning the contents of the rule prior to its indexing and publication. The means that may be used for providing notice of such rules prior to their indexing and publication include, but are not limited to, any one or more of the following means: radio, newspaper, television, signs, mail, telephone, personal notice, electronic transmission, newsletter, or other timely publication.

A rule made effective prior to its indexing and publication in reliance upon the provisions of Iowa Code section 17A.5(2)*"b"*(3) shall include in that rule a statement describing the reasonable efforts that will be used to comply with the requirements of this subrule.

657—28.16(17A) General statements of policy.

28.16(1) *Compilation, indexing, public inspection.* The board shall maintain an official, current, and dated compilation that is indexed by subject containing all of its general statements of policy within the scope of Iowa Code section 17A.2(10)*"a," "c," "f," "g," "h,"* and *"k."* Each addition to, change in, or deletion from the official compilation shall also be dated, indexed, and a record maintained. Except for those portions containing rules governed by Iowa Code section 17A.2(7)*"f,"* or otherwise authorized by law to be kept confidential, the compilation shall be made available for public inspection and copying.

28.16(2) *Enforcement of requirements.* A general statement of policy subject to the requirements of this rule shall not be relied on by the board to the detriment of any person who does not have actual, timely knowledge of the contents of the statement until the requirements of subrule 28.16(1) are satisfied. This provision is inapplicable to the extent necessary to avoid imminent peril to the public health, safety, or welfare.

657—28.17(17A) Review by board of rules.

28.17(1) Any interested person, association, agency, or political subdivision may submit a written request to the administrative rules coordinator requesting the board to conduct a formal review of a specified rule. Upon approval of that request by the administrative rules coordinator, the board shall conduct a formal review of a specified rule to determine whether a new rule should be adopted or the rule should be amended or repealed. The board may refuse to conduct a review if it has conducted such a review of the specified rule within five years prior to the filing of the written request.

28.17(2) In conducting the formal review, the board shall prepare, within a reasonable time, a written report summarizing its findings, its supporting reasons, and any proposed course of action. The report shall include a concise statement of the board's findings regarding the rule's effectiveness in achieving its objectives, including a summary of any available supporting data. The report shall also concisely describe significant written criticisms of the rule received during the previous five years, including a summary of any petitions for waiver of the rule received by the board or granted by the board. The report shall describe alternative solutions to resolve the criticisms of the rule, the reasons any were rejected, and any changes made in the rule in response to the criticisms as well as the reasons for the changes. A copy

of the board's report shall be sent to the administrative rules review committee and the administrative rules coordinator. The report shall also be available for public inspection.

These rules are intended to implement Iowa Code sections 17A.3 to 17A.7 as amended by 1998 Iowa Acts, chapter 1202.

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CHAPTER 29
SALES OF GOODS AND SERVICES

657—29.1(68B) Selling of goods or services by members of the board. The board members shall not sell, either directly or indirectly, any goods or services to individuals, associations, or corporations that are subject to the regulatory authority of the board of pharmacy examiners except as authorized by these rules.

657—29.2(68B) Conditions of consent for board members. Consent shall be given by a majority of the members of the board. Consent shall not be given to a board member to sell goods or services to an individual, association, or corporation regulated by the board unless all of the following conditions are met:

29.2(1) The board member requesting consent does not have authority to determine whether consent should be given.

29.2(2) The board member's duties or functions are not related to the board's regulatory authority over the individual, association, or corporation to whom the goods and services are being sold, or the selling of the good or service does not affect the board member's duties or functions.

29.2(3) The selling of the good or service does not include acting as an advocate on behalf of the individual, association, or corporation to the board.

29.2(4) The selling of the good or service does not result in the board member selling a good or service to the board on behalf of the individual, association, or corporation.

657—29.3(68B) Authorized sales.

29.3(1) A member of the board may sell goods or services to any individual, association, or corporation regulated by any division within the department of public health, other than the board of pharmacy examiners. This consent is granted because the sale of such goods or services does not affect the board member's duties or functions on the board.

29.3(2) A member of the board may sell goods or services to any individual, association, or corporation regulated by the board of pharmacy examiners if those goods or services are routinely provided to the public as part of that person's regular professional practice. This consent is granted because the sale of such goods or services does not affect the board member's duties or functions on the board. In the event an individual, association, or corporation to whom a board member sells goods or services is directly involved in any matter pending before the board, including a disciplinary matter, that board member shall not participate in any deliberation or decision concerning that matter. In the event a complaint is filed with the board concerning the services provided by the board member to a member of the public, that board member is otherwise prohibited by law from participating in any discussion or decision by the board in that case.

29.3(3) Individual application and approval are not required for the sales authorized by this rule unless there are unique facts surrounding a particular sale which would cause the sale to affect the board member's duties or functions, would give the buyer an advantage in dealing with the board, or would otherwise present a conflict of interest.

657—29.4(68B) Application for consent. Prior to selling a good or service to an individual, association, or corporation subject to the regulatory authority of the board of pharmacy examiners, a board member must obtain prior written consent unless the sale is specifically allowed in rule 29.3(68B). The request for consent must be in writing, signed by the board member requesting consent. The application must provide a clear statement of all relevant facts concerning the sale. The application should identify the parties to the sale and the amount of compensation. The application should also explain why the sale should be allowed.

657—29.5(68B) Limitation of consent. Consent shall be in writing and shall be valid only for the activities and the time period specifically described in the consent. Consent can be revoked at any time by a majority vote of the members of the board upon written notice to the board member. A consent

provided under these rules does not constitute authorization for any activity which is a conflict of interest under common law or which would violate any other statute or rule.

It is the responsibility of the board member requesting consent to ensure compliance with all other applicable laws and rules.

These rules are intended to implement Iowa Code section 68B.4.

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CHAPTER 30
IMPAIRED PHARMACY PROFESSIONAL AND TECHNICIAN RECOVERY PROGRAM

657—30.1(155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Association" means a professional pharmaceutical organization, association, or society whose membership consists of pharmacy professionals or pharmacy technicians.

"Board" means the Iowa board of pharmacy examiners.

"Impairment" means the inability of a pharmacy professional to practice pharmacy or of a pharmacy technician to perform related technical functions with reasonable safety and skill as a result of alcohol or drug abuse, dependency, or addiction, or any neuropsychological or physical disorder or disability.

"Impairment program," "recovery program," or *"program"* means an impaired pharmacy professional and technician recovery program established to aid the recovery of impaired pharmacists, pharmacist-interns, or pharmacy technicians.

"Pharmacy professional" or *"professional"* means an Iowa-licensed pharmacist or an Iowa-registered pharmacist-intern.

"Pharmacy technician" or *"technician"* means an Iowa-registered pharmacy technician.

"Program committee" or *"committee"* means an impairment program provider, which may be a peer review committee or a committee of a professional pharmaceutical association or society, which has contracted with the board to provide an impairment program for the assistance of impaired Iowa pharmacy professionals and technicians.

"Recovery contract" means the written document establishing the terms for an individual professional's or technician's participation in the recovery program.

"Self-report" means the written, electronic, or oral notification to the board or a program provider by the professional or technician, prior to the board's receipt of a complaint or report from a second party, that the professional or technician has been or may be diagnosed as having an impairment. A report may be completely self-motivated or may be the result of an interaction with or intervention by another individual and may include acts of poor judgment that need not indicate an impairment or addiction problem but that create a need for medical review and evaluation by appropriate persons. "Self-report" includes those situations where the professional or technician reports diversion or misappropriation of a prescription drug or device for the individual's personal use without proper medical authorization.

657—30.2(155A) Purpose, function, and responsibilities. The board is entrusted with the responsibility to protect the public health and safety through the effective regulation of professionals and technicians engaged in the practice of pharmacy in Iowa. The impaired pharmacy professional and technician recovery program is established to evaluate, assist, and monitor the recovery or rehabilitation of professionals and technicians whose alcohol or chemical dependency or mental or physical disability is potentially threatening to the individual, to the public safety, or to the performance of the individual's duties.

30.2(1) *Assistance to professionals or technicians.* The program assists impaired professionals and technicians in obtaining evaluation, treatment, aftercare, and support from the profession needed to maintain personal and professional integrity.

30.2(2) *Assistance to the board.* The program assists the board in monitoring the activities and professional conduct of impaired professionals and technicians to maintain their integrity and professional standing within the profession of pharmacy.

657—30.3(155A) Program committee and personnel; confidentiality; liability. Activities of program personnel shall be coordinated through the program committee. The committee shall include, but need not be limited to, the following members:

1. One currently licensed Iowa pharmacist;
2. One representative from Drake University College of Pharmacy and Health Sciences;
3. One representative from the University of Iowa College of Pharmacy;

4. One recovery professional;
5. The executive secretary/director of the board or the director's designee;
6. One representative from the program provider.

30.3(1) *Committee meetings.* The program committee shall convene no less than semiannually. All meetings of the program committee shall be closed to the public.

30.3(2) *Proceedings and records confidential.* Records and proceedings of the committee and program personnel reports shall be privileged and confidential, shall not be considered public or open records, and shall not be subject to a subpoena or to a discovery proceeding. Such records and proceedings shall not be disclosed unless the affected professional or technician so requests or as otherwise provided in rule 30.7(155A).

30.3(3) *Immunity from civil liability.* An employee or a member of the board, a committee member, an association or peer review committee, a district or local intervenor, advocate, or monitor, or any other person who furnishes information, data, reports, or records in good faith for the purpose of aiding the impaired professional or technician shall be immune from civil liability. Such person is presumed to have acted in good faith, and any person alleging a lack of good faith has the burden of proof on that issue.

30.3(4) *Program security.* A program provider shall take appropriate steps and shall implement procedures sufficient to ensure the confidentiality of records in the possession of the provider's personnel and the committee. Such security procedures shall include limiting to essential identified personnel access to confidential program information, data, and personally identifiable records.

657—30.4(155A) Identification and referral of impaired professionals and technicians. A professional or technician may self-report an impairment by contacting the board or a program provider. A pharmaceutical peer review committee, a committee of an association, a member of the staff of a college of pharmacy, or any other concerned party may contact a program provider or the board if the reporting person or committee has knowledge that, in the opinion of the reporter, might affect the professional's or technician's competency due to impairment, or that might endanger the public health and safety or the safety of the subject, or that provides grounds for disciplinary action.

30.4(1) *Board referral of self-reporting professional or technician.* The board may refer a self-reporting professional or technician to the committee for evaluation and assistance. The board shall not disclose to the public the identity of a self-reporting professional or technician or any information regarding the individual's impairment if:

a. The individual was not involved in the distribution of controlled substances or legend drugs to other individuals, and

b. The individual agrees to participate in the impairment program, including executing a recovery contract and abiding by the terms of that contract.

30.4(2) *Board referral of other impaired professionals or technicians.* The board may refer to the committee any professional or technician the board has determined to be in need of assistance or support in recovering from the professional's or technician's addiction or impairment. A referral to the committee may be included in the terms of a board order resulting from a contested case hearing, in the terms of a settlement agreement between the board and the professional or technician, or it may be a recommendation of the board to the professional or technician.

657—30.5(155A) Recovery contract requirements. An impaired professional or technician participating in an impairment program shall execute and abide by the terms of a recovery contract with the program committee. Such recovery contract shall identify the requirements and responsibilities of the parties to the contract.

30.5(1) *Duration.* The recovery contract shall specify the length of time the professional or technician shall participate in the program.

30.5(2) *Noncompliance.* The recovery contract shall identify acts and omissions that shall constitute noncompliance with the terms of the contract and shall include the resultant actions of the committee in the event of such noncompliance.

30.5(3) *Practice restrictions.* The recovery contract shall identify restrictions, if any, placed on the professional's or technician's activities regarding the practice of pharmacy and the duration of such restrictions. If the professional or technician is prohibited from practicing pharmacy or assisting in the practice of pharmacy during any period of the recovery contract and is subsequently deemed to be competent to return to the practice of pharmacy, a "back-to-work agreement" shall be prepared and executed, and shall become an addendum to the original program recovery contract. Any restrictions placed on the professional's or technician's practice activities shall be communicated by the professional or technician to the professional's or technician's employer who shall acknowledge receipt of and agreement with those restrictions within 15 days of the execution of the recovery contract or the recovery contract addendum.

30.5(4) *Monitoring provisions.* The recovery contract shall provide for the monitoring and frequency of the professional's or technician's activities and progress. Monitoring may include, but is not limited to:

a. Meetings with aftercare provider or counselor;

b. Meetings with program advocate or monitor;

c. Written or personal reports to the program committee;

d. Body fluid screening and testing or alternate screening and testing measures; and

e. Participation in addiction support group meetings such as Alcoholics Anonymous or Narcotics Anonymous.

30.5(5) *Employer notification.* The recovery contract shall require that the professional or technician notify the professional's or technician's current employer within five days of executing the contract and shall require notification of any prospective employer no later than at the time of an employment interview, if participation in the program is due to illegal use or abuse of licit or illicit drugs or controlled substances or is due to diversion of prescription drugs or controlled substances. If the professional's or technician's current or prospective employment is in pharmacy practice, the pharmacist in charge shall also be notified as provided in this subrule for employer notification.

657—30.6(155A) Program provider contract. The board may contract with one or more associations to provide a recovery program for impaired pharmacy professionals and technicians. Programs shall include, but not be limited to, education, intervention, and posttreatment monitoring. The contract shall provide for payment by the board to the program for expenses incurred in the management and operation of the program but shall not include payment for costs incurred for a participant's evaluation, referral services, treatment, or rehabilitation. Detailed claims or reports identifying program expenses shall be submitted to the executive secretary/director or director's designee not less than annually nor more frequently than monthly.

30.6(1) *Annual reporting.* An association contracting with the board pursuant to this rule shall annually prepare a written detailed accounting of program activities for review by the board. This report shall detail education, intervention, and posttreatment monitoring activities provided under the program.

30.6(2) *Quarterly reporting.* An association contracting with the board pursuant to this rule shall prepare the following reports not less than quarterly nor more frequently than monthly:

a. A confidential written report to the board regarding each participant's diagnosis, prognosis, and recommendations for continuing care, treatment, and supervision. The report shall include the date of last contact and a summary of the last communication with each participant. A case number shall be used to identify each participant, and the report shall be written so as to maintain the anonymity of the participant.

b. A confidential written report to the executive secretary/director or the director's designee regarding each participant's diagnosis, prognosis, and recommendations for continuing care, treatment, and supervision. Participants shall be identified by name. Board staff access to such confidential information, data, and personally identifiable information shall be limited to essential identified personnel.

30.6(3) *Notification of initial contact.* An association contracting with the board pursuant to this rule shall, within 72 hours of receiving information identifying a professional or technician believed to be

impaired, notify the executive secretary/director or the director's designee of the program's involvement with the individual. This notification shall identify the individual involved and, if known, the suspected impairment. Notification may be transmitted via telephone, facsimile, electronic mail, or in person.

30.6(4) *Notification of noncompliance or refusal to participate.* An association contracting with the board pursuant to this rule shall report to the board the name of a professional or technician who refuses to cooperate with the program, who refuses to submit to treatment, or whose impairment is not substantially alleviated through intervention and treatment. Notification shall be in writing, shall identify the individual by name, shall include information regarding the alleged impairment, and shall be submitted to the board within 14 days of knowledge by program personnel of the individual's failure or refusal to participate.

30.6(5) *Notification of imminent danger.* An association contracting with the board pursuant to this rule shall report, within 72 hours, the name of an impaired professional or technician whom the committee or monitor believes to be an imminent danger to either the public or the professional or technician. Notification may be transmitted via telephone or in person.

30.6(6) *Notification of illegal drug distribution to others.* An association contracting with the board pursuant to this rule shall report, within 72 hours, the name of an impaired professional or technician where information regarding the professional's or technician's activities discloses known illegal distribution of controlled substances or legend drugs to other individuals. Notification may be transmitted via telephone, facsimile, electronic mail, or in person. Within 10 days of this notification, all records of the participant in the possession of the program and all information regarding the illegal drug distribution shall be delivered to the executive secretary/director or the director's designee.

30.6(7) *Release of information to executive secretary/director.* An association contracting with the board pursuant to this rule shall, upon request from the executive secretary/director or director's designee, release all records of a participant.

657—30.7(155A) Disclosure of information. The board may disclose information, records, and proceedings concerning an impaired professional or technician participating in a recovery program upon the request of the affected professional or technician, as provided in this rule, or as otherwise provided by law.

30.7(1) *Criminal or administrative disciplinary proceeding.* The board may disclose information, records, and proceedings concerning a program participant in a disciplinary hearing before the board, in a subsequent trial or appeal of a board action or order, or in a criminal proceeding.

30.7(2) *Court order.* The board may disclose information, records, and proceedings concerning a program participant pursuant to an order of a court of competent jurisdiction.

30.7(3) *Other jurisdictions.* The board may disclose information, records, and proceedings concerning a program participant to the pharmacist licensing or disciplinary authorities of other jurisdictions or to the pharmacy technician registering, licensing, or disciplinary authorities of other jurisdictions, as appropriate.

30.7(4) *Practice limitations.* Nothing herein shall prohibit the board from releasing public information regarding the suspension, revocation, cancellation, restriction, or retirement of the license or registration of a participant. Public information may include limitations imposed on the participant's ability to practice pharmacy or to assist in the practice of pharmacy and other relevant information pertaining to the participant that the board deems appropriate and disclosure of which is not otherwise prohibited by law.

657—30.8(155A) Program funds. The board shall assess a surcharge of 10 percent to a pharmacist license fee, a pharmacist license renewal fee, a pharmacist-intern registration fee, a pharmacy technician registration fee, and a pharmacy technician registration renewal fee to fund programs under this chapter. The board may also accept funds made available by the federal or state government or by another public or private source to be used for such programs. Surcharges and funds collected pursuant to this rule shall be delivered to the state treasurer, shall be deposited in a fund separate from the state general fund, and shall be used exclusively to administer programs under this chapter. Expenses that may be paid from this

fund include costs associated with the provision of education, intervention, posttreatment monitoring for program participants, and administrative costs incurred by the board, but shall not include costs incurred for a participant's evaluation, referral services, treatment, or rehabilitation.

These rules are intended to implement Iowa Code Supplement section 155A.39.

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CHAPTER 31
STUDENT LOAN DEFAULT OR NONCOMPLIANCE WITH AGREEMENT FOR PAYMENT OF OBLIGATION

657—31.1(261) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Act" means Iowa Code sections 261.121 to 261.127.

"Board" means the Iowa board of pharmacy examiners.

"Certificate" means a document known as a certificate of noncompliance from the college student aid commission certifying that the named licensee is not in compliance with the terms of an agreement for payment of a student loan obligation.

"Commission" means the college student aid commission.

"Denial notice" means a board notification denying an application for the issuance or renewal of a license as required by the Act.

"License" means a license to practice pharmacy, a registration to practice as a pharmacist-intern, a registration to practice as a pharmacy technician, or a registration to possess, prescribe, dispense, administer, distribute, or otherwise handle controlled substances under Iowa Code chapter 124.

"Licensee" means an individual to whom a license has been issued or who is seeking the issuance of a license.

"Revocation or suspension notice" means a board notification suspending a license for an indefinite or specified period of time or a notification revoking a license as required by the Act.

"Withdrawal certificate" means a document known as a withdrawal of a certificate of noncompliance provided by the commission certifying that the certificate is withdrawn and that the board may proceed with issuance, reinstatement, or renewal of a license.

657—31.2(261) Issuance or renewal of a license—denial. The board shall deny the issuance or renewal of a license upon receipt of a certificate from the commission according to the procedures set forth in Iowa Code sections 261.121 to 261.127.

31.2(1) *Service of denial notice.* Notice shall be served upon the licensee by restricted certified mail, return receipt requested, or by personal service in accordance with the Iowa Rules of Civil Procedure. Alternatively, the licensee may accept service personally or through authorized counsel.

31.2(2) *Effective date of denial.* The effective date of the denial of issuance or renewal of a license, as specified in the notice, shall be 60 days following service of the notice upon the licensee.

31.2(3) *Preparation and service of denial notice.* The executive secretary/director of the board is authorized to prepare and serve the notice upon the licensee.

31.2(4) *Licensee responsible to inform board.* Licensees shall keep the board informed of all court actions and all commission actions taken under or in connection with the Act and shall provide the board copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code section 261.127, all court orders entered in such actions, and any withdrawal certificates issued by the commission.

31.2(5) *Reinstatement following license denial.* All board fees required for application, license renewal, or license reinstatement shall be paid by licensees, and all continuing education requirements shall be met, before a license will be issued, renewed, or reinstated after the board has denied the issuance or renewal of a license pursuant to the Act.

31.2(6) *Effect of filing in district court.* In the event a licensee timely files a district court action following service of a board notice pursuant to Iowa Code sections 261.126 and 261.127, the board shall continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the effective date of the denial of the issuance or renewal of a license, the board shall count the number of days before the action was filed and the number of days after the action was disposed by the court.

31.2(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board deems appropriate in the circumstances, within ten days of the

effective date of the denial of the issuance or renewal of a license and shall similarly notify the licensee when the license is issued or renewed following the board's receipt of a withdrawal certificate.

657—31.3(261) Suspension or revocation of a license. The board shall suspend or revoke a license upon receipt of a certificate from the commission according to the procedures set forth in the Act. This rule shall apply in addition to the procedures set forth in the Act.

31.3(1) *Service of revocation or suspension notice.* Notice shall be served upon the licensee by restricted certified mail, return receipt requested, or by personal service in accordance with the Iowa Rules of Civil Procedure. Alternatively, the licensee may accept service personally or through authorized counsel.

31.3(2) *Effective date of revocation or suspension.* The effective date of the revocation or suspension of a license, as specified in the notice, shall be 60 days following service of the notice upon the licensee.

31.3(3) *Preparation and service of revocation or suspension notice.* The executive secretary/director of the board is authorized to prepare and serve the notice upon the licensee and is directed to notify the licensee that the license will be suspended unless the license is already suspended on other grounds. In the event that the license is on suspension, the executive secretary/director shall notify the licensee of the board's intention to revoke the license.

31.3(4) *Licensee responsible to inform board.* Licensees shall keep the board informed of all court actions and all commission actions taken under or in connection with the Act and shall provide the board copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code section 261.127, all court orders entered in such actions, and any withdrawal certificates issued by the commission.

31.3(5) *Reinstatement following license suspension or revocation.* All board fees required for license renewal or license reinstatement shall be paid by licensees, and all continuing education requirements shall be met, before a license will be renewed or reinstated after the board has suspended a license pursuant to the Act. A licensee whose license to practice pharmacy has been revoked shall complete the examination components as indicated in rule 657—2.10(155A) and shall pay all required examination fees pursuant to rule 657—2.2(147). A licensee whose registration to practice as a pharmacist-intern or as a pharmacy technician or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete application and pay all board fees required for new registration.

31.3(6) *Effect of filing in district court.* In the event a licensee timely files a district court action following service of a board notice pursuant to Iowa Code sections 261.126 and 261.127, the board shall continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the effective date of the suspension or revocation of a license, the board shall count the number of days before the action was filed and the number of days after the action was disposed by the court.

31.3(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board deems appropriate in the circumstances, within ten days of the effective date of the suspension or revocation of a license and shall similarly notify the licensee when the license is reinstated following the board's receipt of a withdrawal certificate.

657—31.4(17A,22,261) Share information. Notwithstanding any statutory confidentiality provision, the board may share information with the commission through manual or automated means for the sole purpose of identifying applicants or licensees subject to enforcement under the Act.

These rules are intended to implement Iowa Code sections 261.121 to 261.127.

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CHAPTER 32
NONPAYMENT OF STATE DEBT

657—32.1(272D) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Act" means Iowa Code chapter 272D.

"Board" means the Iowa board of pharmacy.

"Certificate" means a document known as a certificate of noncompliance provided by the unit certifying that the named licensee has outstanding liability placed with the unit and has not entered into an approved payment plan to pay the liability.

"Denial notice" means a board notification denying an application for the issuance or renewal of a license as required by the Act.

"Liability" means a debt or obligation placed with the unit for collection that is greater than $1000. For purposes of this chapter, "liability" does not include support payments collected pursuant to Iowa Code chapter 252J.

"License" means a license to practice pharmacy, a registration to practice as a pharmacist-intern, a registration to practice as a pharmacy technician, or a registration to possess, prescribe, dispense, administer, distribute, or otherwise handle controlled substances under Iowa Code chapter 124.

"Licensee" means an individual to whom a license has been issued or who is seeking the issuance of a license.

"Revocation or suspension notice" means a board notification suspending a license for an indefinite or specified period of time or a notification revoking a license as required by the Act.

"Unit" means the centralized collection unit of the department of revenue.

"Withdrawal certificate" means a document known as a withdrawal of a certificate of noncompliance provided by the unit certifying that the certificate is withdrawn and that the board may proceed with issuance, reinstatement, or renewal of a license.

657—32.2(272D) Issuance or renewal of a license—denial. The board shall deny the issuance or renewal of a license upon receipt of a certificate from the unit according to the procedures set forth in the Act.

32.2(1) *Service of denial notice.* Notice shall be served upon the licensee by restricted certified mail, return receipt requested, or by personal service in accordance with the Iowa Rules of Civil Procedure. Alternatively, the licensee may accept service personally or through authorized counsel.

32.2(2) *Effective date of denial.* The effective date of the denial of issuance or renewal of a license, as specified in the notice, shall be 60 days following service of the notice upon the licensee.

32.2(3) *Preparation and service of denial notice.* The executive director of the board is authorized to prepare and serve the notice upon the licensee.

32.2(4) *Licensee responsible to inform board.* Licensees shall keep the board informed of all court actions and all unit actions taken under or in connection with the Act and shall provide the board copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code section 272D.9, all court orders entered in such actions, and any withdrawal certificates issued by the unit.

32.2(5) *Reinstatement following license denial.* All board fees required for application, license renewal, or license reinstatement shall be paid by the licensee and all continuing education requirements shall be met before a license will be issued, renewed, or reinstated after the board has denied the issuance or renewal of a license pursuant to the Act.

32.2(6) *Effect of filing in district court.* In the event a licensee timely files a district court action following service of a board notice pursuant to Iowa Code sections 272D.8 and 272D.9, the board shall continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the effective date of the denial of the issuance or renewal of a license, the board shall count the number of days before the action was filed and the number of days after the action was disposed of by the court.

32.2(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board deems appropriate in the circumstances, within ten days of the effective date of the denial of the issuance or renewal of a license and shall similarly notify the licensee when the license is issued or renewed following the board's receipt of a withdrawal certificate.

657—32.3(272D) Suspension or revocation of a license. The board shall suspend or revoke a license upon receipt of a certificate from the unit according to the procedures set forth in the Act. This rule shall apply in addition to the procedures set forth in the Act.

32.3(1) *Service of revocation or suspension notice.* Notice shall be served upon the licensee by restricted certified mail, return receipt requested, or by personal service in accordance with the Iowa Rules of Civil Procedure. Alternatively, the licensee may accept service personally or through authorized counsel.

32.3(2) *Effective date of revocation or suspension.* The effective date of the revocation or suspension of a license, as specified in the notice, shall be 60 days following service of the notice upon the licensee.

32.3(3) *Preparation and service of revocation or suspension notice.* The executive director of the board is authorized to prepare and serve the notice upon the licensee and is directed to notify the licensee that the license will be suspended unless the license is already suspended on other grounds. In the event that the license is on suspension, the executive director shall notify the licensee of the board's intention to revoke the license.

32.3(4) *Licensee responsible to inform board.* Licensees shall keep the board informed of all court actions and all unit actions taken under or in connection with the Act and shall provide the board copies, within seven days of filing or issuance, of all applications filed with the district court pursuant to Iowa Code section 272D.9, all court orders entered in such actions, and any withdrawal certificates issued by the unit.

32.3(5) *Reinstatement following license suspension, revocation, or denial of renewal.* All board fees required for license renewal or license reinstatement shall be paid by the licensee and all continuing education requirements shall be met before a license will be renewed or reinstated after the board has suspended a license pursuant to the Act. A licensee whose license to practice pharmacy has been revoked shall complete the examination components as indicated in rule 657—2.10(155A) and shall pay all required examination fees pursuant to rule 657—2.2(155A). A licensee whose registration to practice as a pharmacist-intern or as a pharmacy technician or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete an application and pay all board fees required for new registration.

32.3(6) *Effect of filing in district court.* In the event a licensee timely files a district court action following service of a board notice pursuant to Iowa Code sections 272D.8 and 272D.9, the board shall continue with the intended action described in the notice upon the receipt of a court order lifting the stay, dismissing the action, or otherwise directing the board to proceed. For purposes of determining the effective date of the suspension or revocation of a license, the board shall count the number of days before the action was filed and the number of days after the action was disposed of by the court.

32.3(7) *Final notification.* The board shall notify the licensee in writing through regular first-class mail, or such other means as the board deems appropriate in the circumstances, within ten days of the effective date of the suspension or revocation of a license and shall similarly notify the licensee when the license is reinstated following the board's receipt of a withdrawal certificate.

657—32.4(17A,22,272D) Share information. Notwithstanding any statutory confidentiality provision, the board may share information with the unit through manual or automated means for the sole purpose of identifying applicants or licensees subject to enforcement under the Act.

These rules are intended to implement Iowa Code chapter 272D.

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CHAPTER 33
Reserved

CHAPTER 34
RULES FOR WAIVERS AND VARIANCES

657—34.1(17A) Definition. For purposes of this chapter, a "waiver" or "variance" means action by the board which suspends, in whole or in part, the requirements or provisions of a rule as applied to an identified person or business on the basis of the particular circumstances of that person or business. For simplicity, the term "waiver" shall include both a waiver and a variance and the term "person" shall include both a person and a business.

657—34.2(17A,124,126,147,155A,205,272C) Scope of chapter. This chapter outlines generally applicable standards and a uniform process for the granting of individual waivers from rules adopted by the board in situations when no other more specifically applicable law provides for waivers. To the extent another more specific provision of law governs the issuance of a waiver from a particular rule, the more specific provision shall supersede this chapter with respect to any waiver from that rule.

657—34.3(17A,124,126,147,155A,205,272C) Applicability of chapter. The board may grant a waiver from a rule only if the board has jurisdiction over the rule and the requested waiver is consistent with applicable statutes, constitutional provisions, or other provisions of law. The board may not waive requirements created or duties imposed by statute.

657—34.4(17A) Criteria for waiver or variance. In response to a petition completed pursuant to rule 34.6(17A), the board may in its sole discretion issue an order waiving in whole or in part the requirements of a rule if the board finds, based on clear and convincing evidence, all of the following:

1. The application of the rule would impose an undue hardship on the person for whom the waiver is requested;
2. The waiver from the requirements of the rule in the specific case would not prejudice the substantial legal rights of any person;
3. The provisions of the rule subject to the petition for a waiver are not specifically mandated by statute or another provision of law; and
4. Substantially equal protection of public health, safety, and welfare will be afforded by a means other than that prescribed in the particular rule for which the waiver is requested.

657—34.5(17A,124,126,147,155A,205,272C) Filing of petition. A petition for a waiver shall be submitted in writing to the board as follows:

34.5(1) *License, registration, or permit application.* If the petition relates to a license, registration, or permit application, the petition shall be made in accordance with the application requirements for the license, registration, or permit in question.

34.5(2) *Contested cases.* If the petition relates to a pending contested case, the petition shall be filed in the contested case proceeding, using the caption of the contested case.

34.5(3) *Other.* If the petition does not relate to a license, registration, or permit application or to a pending contested case, the petition may be submitted to the board's executive secretary/director.

657—34.6(17A) Content of petition. A petition for waiver shall include the following information where applicable and known to the petitioner:

1. The name, address, and telephone number of the person for whom a waiver is requested and the case number of any related contested case.
2. A description and citation of the specific rule from which a waiver is requested.
3. The specific waiver requested, including the precise scope and duration.
4. The relevant facts that the petitioner believes would justify a waiver under each of the four criteria described in rule 34.4(17A). This shall include a signed statement from the petitioner attesting to the accuracy of the facts provided in the petition and a statement of reasons that the petitioner believes will justify a waiver.

5. A history of any prior contacts between the board and the petitioner relating to the regulated activity, license, registration, or permit affected by the proposed waiver. This history shall include a description of each affected license, registration, or permit held by the petitioner and any notices of violation, contested case hearings, or investigative reports relating to the regulated activity, license, registration, or permit within the last five years.

6. Any information known to the petitioner regarding the board's treatment of similar cases.

7. The name, address, and telephone number of any public agency or political subdivision which also regulates the activity in question or which might be affected by the granting of the waiver.

8. The name, address, and telephone number of any person who would be adversely affected by the granting of a petition for waiver.

9. The name, address, and telephone number of any person with knowledge of facts relevant to the proposed waiver.

10. Signed releases authorizing persons with knowledge regarding the request to furnish the board with information relevant to the proposed waiver.

657—34.7(17A) Additional information. Prior to issuing an order granting or denying a waiver, the board may request additional information from the petitioner relative to the petition and surrounding circumstances. If the petition was not filed in a contested case, the board may, on its own motion or at the petitioner's request, schedule a telephonic or in-person meeting between the petitioner and the board's executive secretary/director, a committee of the board, or a quorum of the board.

657—34.8(17A) Notice. The board shall acknowledge a petition upon receipt. The board shall ensure that, within 30 days of the receipt of the petition, notice of the pendency of the petition and a concise summary of its contents have been provided to all persons to whom notice is required by any provision of law. In addition, the board may give notice to other persons. To accomplish this notice provision, the board may require the petitioner to serve the notice on all persons to whom notice is required by any provision of law and provide a written statement to the board attesting that notice has been provided.

657—34.9(17A) Hearing procedures. The provisions of Iowa Code sections 17A.10 through 17A.18A regarding contested case hearings shall apply to any petition for a waiver filed within a contested case. Those provisions shall otherwise apply to agency proceedings for a waiver only when the board so provides by rule or order or is required to do so by statute.

657—34.10(17A) Ruling. An order granting or denying a waiver shall be in writing and shall contain a reference to the particular person and rule or portion thereof to which the order pertains. The order shall include a statement of the relevant facts and reasons upon which the action is based and a description of the precise scope and duration of the waiver if one is issued.

34.10(1) *Board discretion.* The final decision on whether the circumstances justify the granting of a waiver shall be made at the sole discretion of the board upon consideration of all relevant factors. The board shall evaluate each petition for a waiver based on the unique, individual circumstances set out in the petition.

34.10(2) *Burden of persuasion.* The burden of persuasion rests with the petitioner to demonstrate by clear and convincing evidence that the board should exercise its discretion to grant a waiver from a board rule.

34.10(3) *Narrowly tailored exception.* A waiver, if granted, shall provide the narrowest exception possible to the provisions of a rule.

34.10(4) *Administrative deadlines.* When the rule from which a waiver is sought establishes administrative deadlines, the board shall balance the special individual circumstances of the petitioner with the overall goal of uniform treatment of all similarly situated persons.

34.10(5) *Conditions.* The board may place any condition on a waiver that the board finds desirable to protect the public health, safety, and welfare.

34.10(6) *Time period of waiver.* A waiver shall not be permanent unless the petitioner can show that a temporary waiver would be impracticable. If a temporary waiver is granted, there is no automatic right to renewal. At the sole discretion of the board, a waiver may be renewed if the board finds that grounds for the waiver continue to exist.

34.10(7) *Time for ruling.* The board shall grant or deny a petition for a waiver as soon as practicable but, in any event, shall do so within 120 days of its receipt, unless the petitioner agrees to a later date. However, if a petition is filed in a contested case, the board shall grant or deny the petition no later than the time at which the final decision in that contested case is issued.

34.10(8) *When deemed denied.* Failure of the board to grant or deny a petition within the required time period shall be deemed a denial of that petition by the board. However, the board shall remain responsible for issuing an order denying a waiver.

34.10(9) *Service of order.* Within seven days of its issuance, any order issued under these rules shall be transmitted to the petitioner or the person to whom the order pertains and to any other person entitled to such notice by any provision of law.

657—34.11(17A,22) Public availability. All orders granting or denying a waiver petition shall be indexed, filed, and made available for public inspection as provided in Iowa Code section 17A.3. Petitions for waiver and orders granting or denying waiver petitions are public records under Iowa Code chapter 22. Some petitions or orders may contain information the board is authorized or required to keep confidential. The board may accordingly redact confidential information from petitions or orders prior to public inspection.

657—34.12(17A) Summary reports. The board shall semiannually prepare a summary report identifying the rules for which a waiver has been granted or denied, the number of times a waiver was granted or denied for each rule, and a citation to the statutory provisions implemented by these rules. The report shall include a general summary of the reasons justifying the board's actions on waiver requests and, if practicable, shall detail the extent to which the granting of a waiver has affected the general applicability of the rule itself. Copies of this report shall be available for public inspection and shall be provided semiannually to the administrative rules coordinator and the administrative rules review committee.

657—34.13(17A) Cancellation of a waiver. A waiver issued by the board pursuant to this chapter may be withdrawn, canceled, or modified if, after appropriate notice and hearing, the board issues an order finding any of the following:

1. That the petitioner or the person who was the subject of the waiver order withheld or misrepresented material facts relevant to the propriety or desirability of the waiver; or
2. That the alternative means for ensuring adequate protection of the public health, safety and welfare after issuance of the waiver order have been demonstrated to be insufficient; or
3. That the subject of the waiver order has failed to comply with all conditions contained in the order.

657—34.14(17A,124,126,147,155A,205,272C) Violations. Violation of a condition in a waiver order shall be treated as a violation of the particular rule for which the waiver was granted. As a result, the recipient of a waiver under this chapter who violates a condition of the waiver may be subject to the same remedies or penalties as a person who violates the rule at issue.

657—34.15(17A,124,126,147,155A,205,272C) Defense. After the board issues an order granting a waiver, the order is a defense for the person to whom the order pertains, within the terms and the specific facts indicated therein, in any proceeding in which the rule in question is sought to be invoked.

657—34.16(17A) Judicial review. Judicial review of a board's decision to grant or deny a waiver petition may be taken in accordance with Iowa Code chapter 17A.

These rules are intended to implement Iowa Code sections 17A.9A, 17A.22, 22.2, 124.301, 126.17, 147.76, 155A.2, 205.11, 205.13, 272C.3, and 272C.4.

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CHAPTER 35
CONTESTED CASES
[Prior to 5/19/99, see 657—Ch 9]

657—35.1(17A,124,124B,126,147,155A,205,272C) Scope and applicability. This chapter applies to contested case proceedings, including licensee, registrant, or permittee discipline, conducted by the board of pharmacy examiners.

657—35.2(17A,272C) Definitions. Except where otherwise specifically defined by law:

"Board" means the Iowa board of pharmacy examiners.

"Contested case" means a proceeding defined by Iowa Code section 17A.2(5) and includes any matter defined as a no factual dispute contested case under 1998 Iowa Acts, chapter 1202, section 14.

"Issuance" means the date of mailing of a decision or order or date of delivery if service is by other means unless another date is specified in the order.

"Party" means each person or agency named or admitted as a party or properly seeking and entitled as of right to be admitted as a party.

"Presiding officer" means members of the board of pharmacy examiners, or the administrative law judge assigned to preside over the case pursuant to rule 657—35.6(17A,272C).

"Proposed decision" means the presiding officer's recommended findings of fact, conclusions of law, decision, and order in a contested case in which the board did not preside. If the contested case involves licensee or registrant discipline, "proposed decision" means the decision of the panel of the board when the hearing is held before a panel of the board rather than the full board.

657—35.3(17A) Time requirements.

35.3(1) *Computation.* Time shall be computed as provided in Iowa Code subsection 4.1(34).

35.3(2) *Changing time to take action.* For good cause, the presiding officer may extend or shorten the time to take any action, except as precluded by statute or by rule. Except for good cause stated in the record, before extending or shortening the time to take any action, the presiding officer shall afford all parties an opportunity to be heard or to file written arguments.

657—35.4 Reserved.

657—35.5(17A,124B,126,147,155A,205,272C) Notice of hearing.

35.5(1) *Delivery.* Delivery of the notice of hearing constitutes the commencement of the contested case proceeding. Delivery may be executed by:

a. Personal service as provided in the Iowa Rules of Civil Procedure; or

b. Certified mail, return receipt requested; or

c. First-class mail; or

d. Publication, as provided in the Iowa Rules of Civil Procedure.

35.5(2) *Contents.* The notice of hearing shall contain the following information:

a. A statement of the time, place, and nature of the hearing;

b. A statement of the legal authority and jurisdiction under which the hearing is to be held;

c. A reference to the particular sections of the statutes and rules involved;

d. A short and plain statement of the matters asserted. If the board or other party is unable to state the matters in detail at the time the notice is served, the initial notice may be limited to a statement of the issues involved. Thereafter, upon application, a more definite and detailed statement shall be furnished;

e. Identification of all parties including the name, address and telephone number of the person who will act as advocate for the board or the state and of parties' counsel where known;

f. Reference to the procedural rules governing conduct of the contested case proceeding;

g. Reference to the procedural rules governing informal settlement;

h. Identification of the presiding officer, if known. If not known, a description of who will serve as presiding officer (e.g., members of the board, administrative law judge from the department of inspections and appeals); and

i. Notification of the time period in which a party may request, pursuant to Iowa Code section 17A.11 and rule 35.6(17A,272C), that the presiding officer be an administrative law judge.

657—35.6(17A,272C) Presiding officer for nondisciplinary hearings.

35.6(1) *Request for administrative law judge.* Any party may request that an administrative law judge employed by the department of inspections and appeals be assigned to render a proposed decision in a nondisciplinary hearing. The written request shall be filed with the executive secretary/director within 20 days after service of a notice of hearing identifying or describing the presiding officer as the members of the board.

35.6(2) *Grounds for denial.* The executive secretary/director may deny the request only upon a finding that one or more of the following apply:

a. Neither the board nor any member of the board, under whose authority the contested case is to take place, is a named party to the proceeding or a real party in interest to that proceeding.

b. There is a compelling need to expedite issuance of a final decision in order to protect the public health, safety, or welfare.

c. The contested case involves the discipline of a licensee or registrant and therefore must be decided by the board as required by Iowa Code section 272C.6.

d. The case involves significant policy issues of first impression that are inextricably intertwined with the factual issues presented.

e. The demeanor of the witnesses is likely to be dispositive in resolving the disputed factual issues.

f. Funds are unavailable to pay the costs of an administrative law judge and an interagency appeal.

g. The request was not timely filed.

h. The request is not consistent with a specified statute.

35.6(3) *Written ruling.* The executive secretary/director shall issue a written ruling specifying the grounds for the decision within 20 days after a request for an administrative law judge is filed.

35.6(4) *Appeals to board.* Except as provided otherwise by another provision of law, all rulings by an administrative law judge acting as presiding officer are subject to appeal to the board. A party shall seek any available intra-agency appeal in order to exhaust adequate administrative remedies.

35.6(5) *Review of proposed decision.* Unless otherwise provided by law, members of the board, when reviewing a proposed decision upon intra-agency appeal, shall have the powers of and shall comply with the provisions of this chapter which apply to presiding officers.

657—35.7(17A,124B,147,155A,272C) Waiver of procedures. Unless otherwise precluded by law, the parties in a contested case proceeding may waive any provision of this chapter. However, the board in its discretion may refuse to give effect to such a waiver when it deems the waiver to be inconsistent with the public interest.

657—35.8(17A,272C) Telephone or network proceedings. The presiding officer may resolve preliminary procedural motions by telephone conference or by a conference on the Iowa Communications Network (ICN) in which all parties have an opportunity to participate. Other telephone or network proceedings, including the hearing for the contested case proceeding, may be held when appropriate under the circumstances. The presiding officer will determine the location of the parties and witnesses for telephone or network hearings. The convenience of the witnesses or parties, as well as the nature of the case, will be considered when location is chosen.

657—35.9(17A) Disqualification.

35.9(1) *Reasons for withdrawal from participation.* A presiding officer or other person shall withdraw from participation in the making of any proposed or final decision in a contested case if that person:

a. Has a personal bias or prejudice concerning a party or a representative of a party;

b. Has personally investigated, prosecuted or advocated in connection with that case, the specific controversy underlying that case, another pending factually related contested case, or a pending factually related controversy that may culminate in a contested case involving the same parties;

c. Is subject to the authority, direction or discretion of any person who has personally investigated, prosecuted or advocated in connection with that contested case, the specific controversy underlying that contested case, or a pending factually related contested case or controversy involving the same parties;

d. Has acted as counsel to any person who is a private party to that proceeding within the past two years;

e. Has a personal financial interest in the outcome of the case or any other significant personal interest that could be substantially affected by the outcome of the case;

f. Has a spouse or relative within the third degree of relationship that:

(1) Is a party to the case, or an officer, director or trustee of a party;

(2) Is a lawyer in the case;

(3) Is known to have an interest that could be substantially affected by the outcome of the case; or

(4) Is likely to be a material witness in the case; or

g. Has any other legally sufficient cause to withdraw from participation in the decision making in that case.

35.9(2) *"Personally investigated" defined.* The term "personally investigated" means taking affirmative steps to interview witnesses directly or to obtain documents or other information directly. The term "personally investigated" does not include general direction and supervision of assigned investigators, unsolicited receipt of information which is relayed to assigned investigators, review of another person's investigative work product in the course of determining whether there is probable cause to initiate a proceeding, or exposure to factual information while performing other board functions, including fact gathering for purposes other than investigation of the matter which culminates in a contested case. Factual information relevant to the merits of a contested case received by a person who later serves as presiding officer in that case shall be disclosed if required by Iowa Code section 17A.17(3) and subrules 35.9(3) and 35.22(9).

35.9(3) *Determination that withdrawal is not necessary.* In a situation where a presiding officer or other person knows of information which might reasonably be deemed to be a basis for disqualification and decides voluntary withdrawal is unnecessary, that person shall submit by affidavit for the record the relevant information and shall provide for the record a statement of the reasons for the determination that withdrawal is unnecessary.

35.9(4) *Motion for disqualification.* If a party asserts disqualification on any appropriate ground, including those listed in subrule 35.9(1), the party shall file a motion supported by an affidavit pursuant to Iowa Code section 17A.17. The motion shall be filed as soon as practicable after the reason alleged in the motion becomes known to the party. If, during the course of the hearing, a party first becomes aware of evidence of bias or other grounds for disqualification, the party may move for disqualification but must establish the grounds by the introduction of evidence into the record.

If the presiding officer determines that disqualification is appropriate, the presiding officer or other person shall withdraw. If the presiding officer determines that withdrawal is not required, the presiding officer shall enter an order to that effect. A party asserting disqualification may seek an interlocutory appeal under rule 35.24(17A) and seek a stay under rule 35.28(17A,272C).

657—35.10(17A,272C) Consolidation—severance.

35.10(1) *Consolidation.* The presiding officer may consolidate any or all matters at issue in two or more contested case proceedings where:

a. The matters at issue involve common parties or common questions of fact or law;

b. Consolidation would expedite and simplify consideration of the issues involved; and

c. Consolidation would not adversely affect the rights of any of the parties to those proceedings.

35.10(2) *Severance.* The presiding officer may, for good cause shown, order any contested case proceedings or portions thereof severed.

657—35.11(17A,272C) Service and filing of pleadings and other papers.

35.11(1) *Service—when required.* Except where otherwise provided by law, every pleading, motion, document, or other paper filed in a contested case proceeding and every paper relating to discovery in such a proceeding shall be served upon each of the parties of record to the proceeding, including the person designated as advocate or prosecutor for the state or the board, simultaneously with their filing. Except for the original notice of hearing and an application for rehearing as provided in Iowa Code section 17A.16(2), the party filing a document is responsible for service on all parties.

35.11(2) *Service—how made.* Service upon a party represented by an attorney shall be made upon the attorney unless otherwise ordered. Service is made by delivery or by mailing a copy to the person's last-known address. Service by mail is complete upon mailing, except where otherwise specifically provided by statute, rule, or order.

35.11(3) *Filing—when required.* After the notice of hearing, all pleadings, motions, documents or other papers in a contested case proceeding shall be filed with the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. All pleadings, motions, documents or other papers that are required to be served upon a party shall be filed simultaneously with the board of pharmacy examiners.

35.11(4) *Filing—when made.* Except where otherwise provided by law, a document is deemed filed at the time it is delivered to the board, delivered to an established courier service for immediate delivery to the board office, or mailed by first-class mail or state interoffice mail to the board office, so long as there is proof of mailing.

35.11(5) *Proof of mailing.* Proof of mailing includes one of the following:

a. A legible United States Postal Service postmark on the envelope;

b. A certificate of service;

c. A notarized affidavit; or

d. A certification in substantially the following form:

> I certify under penalty of perjury and pursuant to the laws of Iowa that, on (date of mailing), I mailed copies of (describe document) addressed to the Iowa Board of Pharmacy Examiners, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, and to the names and addresses of the parties listed below by depositing the same in (a United States post office mailbox with correct postage properly affixed or state interoffice mail).
>
> _____ _____
>
> Date Signature

657—35.12(17A,272C) Discovery.

35.12(1) *Procedures.* Discovery procedures applicable in civil actions are applicable in contested cases. Unless lengthened or shortened by these rules or by order of the presiding officer, time periods for compliance with discovery shall be as provided in the Iowa Rules of Civil Procedure.

35.12(2) *Motions.* Any motion relating to discovery shall allege that the moving party has previously made a good-faith attempt to resolve the discovery issues involved with the opposing party. The presiding officer shall rule on motions in regard to discovery. Opposing parties shall be afforded the opportunity to respond within ten days of the filing of the motion unless the time is shortened as provided in subrule 35.12(1). The presiding officer may rule on the basis of the written motion and any response, or may order argument on the motion.

35.12(3) *Admissibility of evidence.* Evidence obtained in discovery may be used in the contested case proceeding if that evidence would otherwise be admissible in that proceeding.

657—35.13(17A,272C) Subpoenas.

35.13(1) *Issuance of investigatory subpoenas.*

a. The board's executive secretary/director or designee may, upon the written request of a board investigator or on the executive secretary/director's own initiative, subpoena books, papers, records, and other real evidence which the executive secretary/director determines are necessary for the board

to decide whether to institute a contested case proceeding. In the case of a subpoena for mental health records, each of the following conditions shall be satisfied prior to the issuance of the subpoena:

(1) The nature of the complaint reasonably justifies the issuance of a subpoena;

(2) Adequate safeguards have been established to prevent unauthorized disclosure;

(3) An express statutory mandate, articulated public policy, or other recognizable public interest favors access; and

(4) The patient was notified and an attempt was made to secure an authorization from the patient for release of the records at issue.

b. A written request for a subpoena or the executive secretary/director's written memorandum in support of the issuance of a subpoena shall contain the following:

(1) The name and address of the person to whom the subpoena will be directed;

(2) A specific description of the books, papers, records or other real evidence requested;

(3) An explanation of why the documents sought to be subpoenaed are necessary for the board to determine whether it should institute a contested case proceeding; and

(4) In the case of a subpoena request for mental health records, confirmation that the conditions described in subrule 35.13(1), paragraph *"a,"* have been satisfied.

c. Each subpoena shall contain:

(1) The name and address of the person to whom the subpoena is directed;

(2) A description of the books, papers, records or other real evidence requested;

(3) The date, time, and location for production or inspection and copying;

(4) The time within which a motion to quash or modify the subpoena must be filed;

(5) The signature, address and telephone number of the executive secretary/director or designee;

(6) The date of issuance;

(7) A return of service.

d. Any person who is aggrieved or adversely affected by compliance with the subpoena who desires to challenge the subpoena shall, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days, file with the board a motion to quash or modify the subpoena. The motion shall describe the legal reasons why the subpoena should be quashed or modified and may be accompanied by legal briefs or factual affidavits.

e. Upon receipt of a timely motion to quash or modify a subpoena, the board may request an administrative law judge to hold an argument and issue a decision, or the board may hold the argument and issue a decision. The administrative law judge or the board may quash or modify the subpoena, deny the motion, or issue an appropriate protective order.

f. A person aggrieved by a ruling of an administrative law judge who desires to challenge the ruling shall appeal the ruling to the board in accordance with the procedure applicable to intra-agency appeals of proposed decisions set forth in rule 35.26(17A,124B,126,147,155A,205, 272C), provided that all of the time frames are reduced by one-half.

g. If the person contesting the subpoena is not the person under investigation, the board's decision is final for purposes of judicial review. If the person contesting the subpoena is the person under investigation, the board's decision is not final for purposes of judicial review until either the person is notified the investigation has been concluded with no formal action or there is a final decision in the contested case.

35.13(2) *Issuance of subpoenas in a contested case.*

a. Subpoenas issued in a contested case may compel the attendance of witnesses at depositions or hearing, and may compel the production of books, papers, records, and other real evidence. A command to produce evidence or to permit inspection may be joined with a command to appear at deposition or hearing, or may be issued separately. Upon written request, the executive secretary/director or designee shall issue subpoenas. A request for a subpoena of patient records must confirm the conditions described in subrule 35.13(1), paragraph *"a,"* prior to the issuance of the subpoena.

b. A request for a subpoena shall include the following information, as applicable, unless the subpoena is requested to compel testimony or documents for rebuttal or impeachment purposes:

(1) The name, address, and telephone number of the person requesting the subpoena;

(2) The name and address of the person to whom the subpoena shall be directed;

(3) The date, time, and location at which the person shall be commanded to attend and give testimony;

(4) Whether the testimony is requested in connection with a deposition or hearing;

(5) A description of the books, papers, records, or other real evidence requested;

(6) The date, time, and location for production or inspection and copying; and

(7) In the case of a subpoena request for mental health records, confirmation that the conditions described in subrule 35.13(1), paragraph *"a,"* have been satisfied.

c. Each subpoena shall contain, as applicable:

(1) The caption of the case;

(2) The name, address, and telephone number of the person who requested the subpoena;

(3) The name and address of the person to whom the subpoena is directed;

(4) The date, time, and location at which the person is commanded to appear;

(5) Whether the testimony is commanded in connection with a deposition or hearing;

(6) A description of the books, papers, records or other real evidence the person is commanded to produce;

(7) The date, time, and location for production or inspection and copying;

(8) The time within which a motion to quash or modify the subpoena must be filed;

(9) The signature, address, and telephone number of the executive secretary/director or designee;

(10) The date of issuance;

(11) A return of service.

d. Unless a subpoena is requested to compel testimony or documents for rebuttal or impeachment purposes, the executive secretary/director or designee shall mail copies of all subpoenas to the parties to the contested case. The person who requested the subpoena is responsible for serving the subpoena upon the subject of the subpoena.

e. Any person who is aggrieved or adversely affected by compliance with the subpoena, or any party to the contested case who desires to challenge the subpoena, shall, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days, file with the board a motion to quash or modify the subpoena. The motion shall describe the legal reasons why the subpoena should be quashed or modified, and may be accompanied by legal briefs or factual affidavits.

f. Upon receipt of a timely motion to quash or modify a subpoena, the board may request an administrative law judge to hold an argument and issue a decision, or the board may hold the argument and issue a decision. The administrative law judge or the board may quash or modify the subpoena, deny the motion, or issue an appropriate protective order.

g. A person aggrieved by a ruling of an administrative law judge who desires to challenge the ruling shall appeal the ruling to the board in accordance with the procedure applicable to intra-agency appeals of proposed decisions set forth in rule 35.26(17A,124B,126,147,155A,205,272C), provided that all of the time frames are reduced by one-half.

h. If the person contesting the subpoena is not the person under investigation, the board's decision is final for purposes of judicial review. If the person contesting the subpoena is the person under investigation, the board's decision is not final for purposes of judicial review until there is a final decision in the contested case.

35.13(3) *Refusal to obey subpoena.* In the event of a refusal to obey a subpoena, the board may petition the district court for its enforcement. Upon proper showing, the district court shall order the person to obey the subpoena and, if the person fails to obey the order of the court, the person may be found guilty of contempt of court.

657—35.14(17A,272C) Motions.

35.14(1) *Form.* No technical form for motions is required. However, prehearing motions must be in writing, state the grounds for relief, and state the relief sought.

35.14(2) *Timely response.* Any party may file a written response to a motion within ten days after the motion is served, unless the time period is extended or shortened by rules of the board or the presiding

officer. The presiding officer may consider a failure to respond within the required time period in ruling on a motion.

35.14(3) *Oral argument.* The presiding officer may schedule oral argument on any motion.

35.14(4) *Timely filing.* Motions pertaining to the hearing, except motions for summary judgment, shall be filed and served at least ten days prior to the date of hearing unless there is good cause for permitting later action or the time for such action is lengthened or shortened by rule of the board or an order of the presiding officer.

657—35.15(17A,272C) Prehearing conference.

35.15(1) *Request or order for conference.* Any party may request a prehearing conference. A written request for prehearing conference or an order for prehearing conference on the presiding officer's own motion shall be filed not less than seven days prior to the hearing date. A prehearing conference shall be scheduled not less than three business days prior to the hearing date.

Written notice of the prehearing conference shall be given by the executive secretary/director to all parties. For good cause the presiding officer may permit variances from this rule.

35.15(2) *Witness and exhibit lists.* Each party shall bring to the prehearing conference:

a. A final list of the witnesses who the party anticipates will testify at hearing. Witnesses not listed may be excluded from testifying unless there was good cause for the failure to include their names; and

b. A final list of exhibits that the party anticipates will be introduced at hearing. Exhibits other than rebuttal exhibits that are not listed may be excluded from admission into evidence unless there was good cause for the failure to include them.

c. Witness or exhibit lists may be amended subsequent to the prehearing conference within the time limits established by the presiding officer at the prehearing conference. Any such amendments must be served on all parties.

35.15(3) *Effect of conference.* In addition to the requirements of subrule 35.15(2), the parties at a prehearing conference may:

a. Enter into stipulations of law or fact;

b. Enter into stipulations on the admissibility of exhibits;

c. Identify matters that the parties intend to request be officially noticed;

d. Enter into stipulations for waiver of any provision of law; and

e. Consider any additional matters that will expedite the hearing.

35.15(4) *Conducted by telephone.* Prehearing conferences shall be conducted by telephone unless otherwise ordered. Parties shall exchange and receive witness and exhibit lists in advance of a prehearing conference.

657—35.16(17A,272C) Continuances. Unless otherwise provided, applications for continuances shall be made to the presiding officer or, in the case of a license or registrant disciplinary hearing, to the executive secretary/director.

35.16(1) *Requirements of application.* A written application for a continuance shall:

a. Be made at the earliest possible time and no less than seven days before the hearing except in case of unanticipated emergencies;

b. State the specific reasons for the request; and

c. Be signed by the requesting party or the party's representative.

An oral application for a continuance may be made if the presiding officer, or in a disciplinary hearing the executive secretary/director, waives the requirement for a written motion. However, a party making such an oral application for a continuance must confirm that request by written application within five days after the oral request unless that requirement is waived by the presiding officer or, in a disciplinary hearing, by the executive secretary/director. No application for continuance shall be made or granted without notice to all parties except in an emergency where notice is not feasible. The board may waive notice of such requests for a particular case or an entire class of cases.

35.16(2) *Consideration of application.* In determining whether to grant a continuance, the presiding officer, or in a disciplinary hearing the executive secretary/director, may consider:

a. Prior continuances;
b. The interests of all parties;
c. The likelihood of informal settlement;
d. The existence of an emergency;
e. Any objection;
f. Any applicable time requirements;
g. The existence of a conflict in the schedules of counsel, parties, or witnesses;
h. The timeliness of the request; and
i. Other relevant factors.

The presiding officer, or in a disciplinary hearing the executive secretary/director, may require documentation of any grounds for continuance.

657—35.17(17A) Withdrawals. A party requesting a contested case proceeding may withdraw that request prior to the hearing only in accordance with board rules. Unless otherwise provided, a withdrawal shall be with prejudice.

657—35.18 Reserved.

657—35.19(17A,124B,126,147,155A,205,272C) Hearing procedures in contested cases.

35.19(1) *Presiding officer.* The presiding officer presides at the hearing and may rule on motions, require briefs, issue a proposed decision, and issue such orders and rulings as will ensure the orderly conduct of the proceedings.

35.19(2) *Objections.* All objections shall be timely made and stated on the record.

35.19(3) *Right of participation or representation.* Parties have the right to participate or to be represented in all hearings or prehearing conferences related to their case. Partnerships, corporations, or associations may be represented by any member, officer, director, or duly authorized agent. An attorney or another person authorized by law may represent any party.

35.19(4) *Rights of all parties.* Subject to terms and conditions prescribed by the presiding officer, parties have the right to introduce evidence on issues of material fact, cross-examine witnesses present at the hearing as necessary for a full and true disclosure of the facts, present evidence in rebuttal, and submit briefs and engage in oral argument.

35.19(5) *Disorderly conduct.* The presiding officer shall maintain the decorum of the hearing and may refuse to admit or may expel anyone whose conduct is disorderly.

35.19(6) *Sequestering witnesses.* Witnesses may be sequestered during the hearing.

35.19(7) *Conduct of hearing.* The presiding officer shall conduct the hearing in the following manner:

a. The presiding officer shall give an opening statement briefly describing the nature of the proceedings;
b. The parties shall be given an opportunity to present opening statements;
c. Parties shall present their cases in the sequence determined by the presiding officer;
d. Each witness shall be sworn or affirmed by the presiding officer or the court reporter, and be subject to examination and cross-examination. The presiding officer may limit questioning in a manner consistent with law;
e. When all parties and witnesses have been heard, parties may be given the opportunity to present final arguments.

35.19(8) *Administrative law judge.* A license disciplinary hearing shall be conducted by a qualified administrative law judge and either a quorum of the board or a panel of not less than three pharmacist members of the board. The administrative law judge's duties shall include:

a. Opening the record and receiving appearances.
b. Administering oaths.
c. Entering notice of the hearing into the record.
d. Receiving testimony and exhibits presented by the parties.

e. At the administrative law judge's discretion, interrogating witnesses.

f. Making initial rulings on objections and motions.

g. Closing the hearing.

h. Participating in board or panel deliberations and preparing an order containing findings of fact and conclusions of law in accordance with the board's or panel's decisions.

35.19(9) *Written decision.* In a license disciplinary hearing, the administrative law judge shall prepare in writing the proposed decision of the panel or the final decision of the board, as applicable. Such decisions shall:

a. Be in writing and signed by the board chairperson or the chairperson's designee.

b. Set forth the issues, a brief history of the case, findings of fact, the reasons for the decision, and the actual decision.

c. Be based upon the kind of evidence on which reasonably prudent persons are accustomed to rely for the conduct of their serious affairs.

d. Be delivered to the licensee, permittee, or registrant by personal service or by certified mail, return receipt requested.

35.19(10) *Hearings open to the public.* License, permit, or registration disciplinary hearings shall be open to the public except as provided in Iowa Code section 272C.6 and Iowa Code chapter 21.

35.19(11) *Decisions available for public inspection.* Copies of all decisions of the board shall be kept on file for public inspection at the office of the board pursuant to 657—Chapter 14.

35.19(12) *Proceedings recorded.* Oral proceedings in connection with a hearing in a contested case shall be recorded either by mechanized means or by certified shorthand reporters. These records shall be kept in the board office for a period of five years following the date of the hearing.

35.19(13) *Board chairperson.* The chairperson of the board shall have the right to vote in all administrative hearings.

35.19(14) *Final decision.* When a quorum of the board presides over the reception of the evidence at the hearing, its decision is a final decision.

657—35.20(17A,272C) Evidence.

35.20(1) *Ruling on admissibility.* The presiding officer shall rule on admissibility of evidence and may, where appropriate, take official notice of facts in accordance with all applicable requirements of law.

35.20(2) *Stipulation.* Stipulation of facts is encouraged. The presiding officer may make a decision based on stipulated facts.

35.20(3) *Issues limited.* Evidence in the proceeding shall be confined to the issues as to which the parties received notice prior to the hearing unless the parties waive their right to such notice or the presiding officer determines that good cause justifies expansion of the issues. If the presiding officer decides to admit evidence on issues outside the scope of the notice over the objection of a party who did not have actual notice of those issues, that party, upon timely request, shall receive a continuance sufficient to amend pleadings and to prepare on the additional issue.

35.20(4) *Admissible evidence.* Irrelevant, immaterial, and unduly repetitious evidence should be excluded. A finding will be based upon the kind of evidence upon which reasonably prudent persons are accustomed to rely for the conduct of their serious affairs, and may be based upon such evidence even if it would be inadmissible in a jury trial.

35.20(5) *Exhibits.* The party seeking admission of an exhibit must provide opposing parties with an opportunity to examine the exhibit prior to the ruling on its admissibility. Copies of documents should normally be provided to opposing parties. All exhibits admitted into evidence shall be appropriately marked and be made part of the record.

35.20(6) *Objection.* Any party may object to specific evidence or may request limits on the scope of any examination or cross-examination. A brief statement of the grounds upon which it is based shall accompany the objection. The objection, the ruling on the objection, and the reasons for the ruling shall be noted in the record. The presiding officer may rule on the objection at the time it is made or may reserve a ruling until the written decision.

35.20(7) *Offer of proof.* Whenever evidence is ruled inadmissible, the party offering that evidence may submit an offer of proof on the record. The party making the offer of proof for excluded oral testimony shall briefly summarize the testimony or, with permission of the presiding officer, present the testimony. If the excluded evidence consists of a document or exhibit, it shall be marked as part of an offer of proof and inserted in the record.

35.20(8) and **35.20(9)** Rescinded IAB 11/13/02, effective 12/18/02.

657—35.21(17A,272C) Default.

35.21(1) *Failure to appear.* If a party fails to appear or participate in a contested case proceeding after proper service of notice, the presiding officer may, if no adjournment is granted, enter a default decision or proceed with the hearing and render a decision in the absence of the party.

35.21(2) *Motion for default.* Where appropriate and not contrary to law, any party may move for default against a party who has requested the contested case proceeding and has failed to file a required pleading or has failed to appear after proper service.

35.21(3) *Motion to vacate.* A default decision or a decision rendered on the merits after a party has failed to appear or participate in a contested case proceeding shall become final board action unless within 15 days after the date of notification or mailing of the decision a motion to vacate is filed and served on all parties or unless an appeal of a decision on the merits is timely initiated within the time provided by rule 35.26(17A,124B,126,147,155A,205,272C). A motion to vacate must state all facts relied upon by the moving party which establish that good cause existed for that party's failure to appear or participate at the contested case proceeding. Each fact so stated must be substantiated by at least one sworn affidavit of a person with personal knowledge of each such fact, which affidavit(s) must be attached to the motion.

35.21(4) *Appeal.* The time for further appeal of a decision for which a timely motion to vacate has been filed is stayed pending a decision on the motion to vacate.

35.21(5) *Proof of good cause.* Properly substantiated and timely filed motions to vacate shall be granted only for good cause shown. The burden of proof as to good cause is on the moving party. Adverse parties shall have ten days to respond to a motion to vacate. Adverse parties shall be allowed to conduct discovery as to the issue of good cause and to present evidence on the issue prior to a decision on the motion if a request to do so is included in that party's response.

35.21(6) *"Good cause" defined.* "Good cause," for purposes of this rule, shall have the same meaning as "good cause" for setting aside a default judgment under Iowa Rule of Civil Procedure 1.977.

35.21(7) *Appeal of decision on motion to vacate.* A decision denying a motion to vacate is subject to further appeal within the time limit allowed for further appeal of a decision on the merits in the contested case proceeding. A decision granting a motion to vacate is subject to interlocutory appeal by the adverse party pursuant to rule 35.24(17A,272C).

35.21(8) *Notice of hearing.* If a motion to vacate is granted and no timely interlocutory appeal has been taken, the presiding officer shall issue another notice of hearing and the contested case shall proceed accordingly.

35.21(9) *Default decision.* A default decision may award any relief consistent with the request for relief made in the petition and embraced in its issues but, unless the defaulting party has appeared, it cannot exceed the relief demanded.

35.21(10) *Default decision effective.* A default decision may provide either that the default decision is to be stayed pending a timely motion to vacate or that the default decision is to take effect immediately, subject to a request for stay under rule 35.28(17A,272C).

657—35.22(17A,272C) Ex parte communication.

35.22(1) *Prohibited communications.* Unless required for the disposition of ex parte matters specifically authorized by statute, following issuance of the notice of hearing there shall be no communication, directly or indirectly, between the presiding officer and any party or representative of any party or any other person with a direct or indirect interest in such case in connection with any issue of fact or law in the case except upon notice and opportunity for all parties to participate. This does not prohibit persons jointly assigned such tasks from communicating with each other. Nothing in this

provision is intended to preclude the presiding officer from communicating with members of the board or seeking the advice or help of persons other than those with a personal interest in, or those engaged in personally investigating as defined in subrule 35.9(2), prosecuting, or advocating in, either the case under consideration or a pending factually related case involving the same parties as long as those persons do not directly or indirectly communicate to the presiding officer any ex parte communications they have received of a type that the presiding officer would be prohibited from receiving or that furnish, augment, diminish, or modify the evidence in the record.

35.22(2) *Duration of prohibition.* Prohibitions on ex parte communications commence with the issuance of the notice of hearing in a contested case and continue for as long as the case is pending.

35.22(3) *"Ex parte" defined.* Written, oral, or other forms of communication are "ex parte" if made without notice and opportunity for all parties to participate.

35.22(4) *Authorized communications.* To avoid prohibited ex parte communications, notice must be given in a manner reasonably calculated to give all parties a fair opportunity to participate. Notice of written communications shall be provided in compliance with rule 35.11(17A,272C) and may be supplemented by telephone, facsimile, electronic mail, or other means of notification. Where permitted, oral communications may be initiated through conference telephone call including all parties or their representatives.

35.22(5) *Communications between presiding officers.* Persons who jointly act as presiding officers in a pending contested case may communicate with each other without notice or opportunity for parties to participate.

35.22(6) *Others authorized to communicate with presiding officer.* The executive secretary/director or other persons may be present in deliberations or otherwise advise the presiding officer without notice or opportunity for parties to participate as long as they are not disqualified from participating in the making of a proposed or final decision under any provision of law and they comply with subrule 35.22(1).

35.22(7) *Communications not prohibited.* Communications with the presiding officer involving uncontested scheduling or procedural matters do not require notice or opportunity for parties to participate. Parties should notify other parties prior to initiating such contact with the presiding officer when feasible and shall notify other parties when seeking to continue hearings or other deadlines pursuant to rule 35.16(17A,272C).

35.22(8) *Disclosure of prohibited communications received during pendency of case.* A presiding officer who receives a prohibited ex parte communication during the pendency of a contested case must initially determine if the effect of the communication is so prejudicial that the presiding officer should be disqualified.

a. If the presiding officer determines that disqualification is warranted, a copy of any prohibited written communication, all written responses to the communication, a written summary stating the substance of any prohibited oral or other communication not available in written form for disclosure, all responses made, and the identity of each person from whom the presiding officer received a prohibited ex parte communication shall be submitted for inclusion in the record under seal by protective order.

b. If the presiding officer determines that disqualification is not warranted, such documents shall be submitted for inclusion in the record and served on all parties.

c. Any party desiring to rebut the prohibited communication must be allowed the opportunity to do so upon written request filed within ten days after notice of the communication.

35.22(9) *Disclosure of prohibited communications received prior to assignment as presiding officer.* Promptly after being assigned to serve as presiding officer at any stage in a contested case proceeding, a presiding officer shall disclose to all parties material factual information received through ex parte communication prior to such assignment unless the factual information has already been or shortly will be disclosed pursuant to Iowa Code section 17A.13(2) or through discovery. Factual information contained in an investigative report or similar document need not be separately disclosed by the presiding officer as long as such documents have been or will shortly be provided to the parties.

35.22(10) *Sanctions for violation.* The presiding officer may render a proposed or final decision imposing appropriate sanctions for violations of this rule, including default, a decision against the offending party, censure, or suspension or revocation of the privilege to practice before the board.

Violation of ex parte communication prohibitions by board personnel shall be reported to the executive secretary/director for possible sanctions including censure, suspension, dismissal, or other disciplinary action.

657—35.23(17A,272C) Recording costs. Upon request, the board shall provide a copy of the whole or any portion of the record at cost. The requesting party shall pay the cost of preparing a copy of the record or of transcribing the hearing record. Parties who request that a hearing be recorded by certified shorthand reporters rather than by electronic means shall bear the cost of that recordation, unless otherwise provided by law.

657—35.24(17A,272C) Interlocutory appeals. If the board is not serving as the presiding officer, upon written request of a party or on its own motion, the board may review an interlocutory order of the presiding officer. In determining whether to do so, the board shall weigh the extent to which its granting the interlocutory appeal would expedite final resolution of the case and the extent to which review of that interlocutory order by the board at the time it reviews the proposed decision of the presiding officer would provide an adequate remedy. Any request for interlocutory review must be filed within 14 days of issuance of the challenged order, but no later than the time for compliance with the order or the date of hearing, whichever is first.

657—35.25(17A) Final decision.

35.25(1) *Presiding officer—board.* When a quorum of the board presides over the reception of evidence at the hearing, the board's decision is a final decision.

35.25(2) *Presiding officer—not the board.* When the board does not preside at the reception of evidence, the presiding officer shall make a proposed decision. The proposed decision becomes the final decision of the board without further proceedings unless there is an appeal to, or review on motion of, the board within the time provided in rule 35.26(17A,124B,126,147,155A,205,272C).

657—35.26(17A,124B,126,147,155A,205,272C) Appeals and review.

35.26(1) *Appeal by party.* Any adversely affected party may appeal a proposed decision to the board within 30 days after issuance of the proposed decision.

35.26(2) *Review.* The board may initiate review of a proposed decision on its own motion at any time within 30 days following the issuance of such a decision.

35.26(3) *Notice of appeal.* An appeal of a proposed decision is initiated by filing a timely notice of appeal with the board. The appealing party or a representative of that party shall sign the notice of appeal and shall include a certificate of service. The notice shall specify:

a. The parties initiating the appeal;

b. The proposed decision or order appealed from;

c. The specific findings or conclusions to which exception is taken and any other exceptions to the decision or order;

d. The relief sought;

e. The grounds for relief.

35.26(4) *Requests to present additional evidence.* A party may request the taking of additional evidence only by establishing that the evidence is material, that good cause existed for the failure to present the evidence at the hearing, and that the party has not waived the right to present the evidence. A written request to present additional evidence must be filed with the notice of appeal or, by a non-appealing party, within 14 days of service of the notice of appeal. The board may remand a case to the presiding officer for further hearing or may itself preside at the taking of additional evidence.

35.26(5) *Scheduling.* The board of pharmacy examiners shall issue a schedule for consideration of the appeal.

35.26(6) *Briefs and arguments.* Unless otherwise ordered, within 20 days of the notice of appeal or order for review, each appealing party may file exceptions and briefs. Within 20 days thereafter, any party may file a responsive brief. Briefs shall cite any applicable legal authority and specify relevant

portions of the record in that proceeding. Written requests to present oral argument shall be filed with the briefs. The board may resolve the appeal on the briefs or provide an opportunity for oral argument. The board may shorten or extend the briefing period as appropriate.

657—35.27(17A,124B,126,147,155A,205,272C) Applications for rehearing.

35.27(1) *By whom filed.* Any party to a contested case proceeding may file an application for rehearing from a final order.

35.27(2) *Content of application.* The application for rehearing shall state on whose behalf it is filed, the specific grounds for rehearing, and the relief sought. In addition, the application shall state whether the applicant desires reconsideration of all or part of the board decision on the existing record and whether, on the basis of the grounds enumerated in subrule 35.26(4), the applicant requests an opportunity to submit additional evidence.

35.27(3) *Time of filing.* The application shall be filed with the board of pharmacy examiners within 20 days after issuance of the final decision.

35.27(4) *Notice to other parties.* A copy of the application shall be timely mailed by the applicant to all parties of record not joining therein. If the application does not contain a certificate of service, the board of pharmacy examiners shall serve copies on all parties.

35.27(5) *Disposition.* Any application for a rehearing shall be deemed denied unless the board grants the application within 20 days after its filing.

657—35.28(17A,272C) Stays of board actions.

35.28(1) *When available.*

a. Any party to a contested case proceeding may petition the board of pharmacy examiners for a stay of an order issued in that proceeding or for other temporary remedies, pending review by the board. The petition shall be filed with the notice of appeal and shall state the reasons justifying a stay or other temporary remedy. The board may rule on the stay or authorize the presiding officer to do so.

b. Any party to a contested case proceeding may petition the board of pharmacy examiners for a stay or other temporary remedies, pending judicial review of all or part of that proceeding. The petition shall state the reasons justifying a stay or other temporary remedy.

35.28(2) *When granted.* In determining whether to grant a stay, the presiding officer or board shall consider the following factors:

a. The extent to which the applicant is likely to prevail when the court finally disposes of the matter;

b. The extent to which the applicant will suffer irreparable injury if relief is not granted;

c. The extent to which the grant of relief to the applicant will substantially harm other parties to the proceedings;

d. The extent to which the public interest relied on by the board is sufficient to justify the board's action in the circumstances.

35.28(3) *Vacation.* The issuing authority may vacate a stay upon application of the board or any other party.

657—35.29(17A,272C) No factual dispute contested cases. If the parties agree that no dispute of material fact exists as to a matter that would be a contested case if such a dispute of fact existed, the parties may present all relevant admissible evidence either by stipulation or otherwise as agreed by the parties, without necessity for the production of evidence at an evidentiary hearing. If such agreement is reached, a jointly submitted schedule detailing the method and timetable for submission of the record, briefs and oral argument should be submitted to the presiding officer for approval as soon as practicable.

657—35.30(17A,124B,126,147,155A,205,272C) Emergency adjudicative proceedings.

35.30(1) *Necessary emergency action.* To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the board may issue a written order in compliance with Iowa Code section 17A.18 to suspend a license,

registration, or permit in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the board by emergency adjudicative order. Before issuing an emergency adjudicative order, the board shall consider factors including, but not limited to, the following:

a. Whether there has been a sufficient factual investigation to ensure that the board is proceeding on the basis of reliable information;

b. Whether the specific circumstances that pose immediate danger to the public health, safety, or welfare have been identified and determined to be continuing;

c. Whether the person required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety, or welfare;

d. Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety, or welfare; and

e. Whether the specific action contemplated by the board is necessary to avoid the immediate danger.

35.30(2) *Issuance of order.*

a. An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the agency's decision to take immediate action.

b. The written emergency adjudicative order shall be immediately delivered to persons who are required to comply with the order by utilizing one or more of the following procedures:

(1) Personal delivery;

(2) Certified mail, return receipt requested, to the last address on file with the board;

(3) Certified mail to the last address on file with the board;

(4) First-class mail to the last address on file with the board; or

(5) Facsimile. Facsimile transmission may be used as the sole method of delivery if the person required to comply with the order has filed a written request that board orders be sent by facsimile and has provided a facsimile telephone number for that purpose.

c. To the degree practicable, the board shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

35.30(3) *Oral notice.* Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the board shall make reasonable immediate efforts to contact by telephone the persons who are required to comply with the order.

35.30(4) *Completion of proceedings.* After the issuance of an emergency adjudicative order, the board shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

Issuance of a written emergency adjudicative order shall include notification of the date on which board proceedings are scheduled for hearing. After issuance of an emergency adjudicative order, continuance of further board proceedings to a later date will be granted only in compelling circumstances upon application in writing.

These rules are intended to implement Iowa Code sections 17A.10 to 17A.23, 124.304, 124B.12, 126.17, 147.96, 155A.6, 155A.12, 155A.13A, 155A.15 to 155A.18, 155A.26, 205.11, 272C.3 to 272C.6, 272C.9, and 272C.10.

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CHAPTER 36
DISCIPLINE

657—36.1(147,155A,272C) Authority and grounds for discipline.

36.1(1) *Jurisdiction of the board.* The board has the authority to impose discipline for any violations of Iowa Code chapters 124, 124A, 124B, 126, 147, 155A, 205, and 272C or the rules promulgated thereunder.

36.1(2) *Disciplinary sanctions.* The board has the authority to impose the following disciplinary sanctions:

a. Revocation of a registration, a permit, or a license issued by the board.

b. Suspension of a registration, a permit, or a license issued by the board until further order of the board or for a specified period.

c. Nonrenewal of a registration, a permit, or a license issued by the board.

d. Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods or acts.

e. Probation.

f. Require a pharmacist or a pharmacist-intern to complete additional education or training.

g. Require a pharmacist to successfully complete any reexamination for licensure.

h. Order a pharmacist, pharmacist-intern, or pharmacy technician to undergo a physical or mental examination.

i. Impose civil penalties not to exceed $25,000.

j. Issue citation and warning.

k. Such other sanctions allowed by law as may be appropriate.

36.1(3) *Considerations in determining sanctions.* The board may consider the following factors in determining the nature and severity of the disciplinary sanction to be imposed:

a. The relative seriousness of the violation as it relates to assuring the citizens of this state a high standard of professional care.

b. The facts of the particular violation.

c. Any extenuating circumstances or other countervailing considerations.

d. Number of prior violations or complaints.

e. Seriousness of prior violations or complaints.

f. Whether remedial action has been taken.

g. Any other factors as may reflect upon the competency, ethical standards, and professional conduct of the licensee, registrant, or permittee.

36.1(4) *Grounds for discipline.* The board may impose any of the disciplinary sanctions set out in subrule 36.1(2) when the board determines that the licensee, registrant, or permittee is guilty of the following acts or offenses:

a. Fraud in procuring a license. Fraud in procuring a license includes but is not limited to an intentional perversion of the truth in making application for a license to practice pharmacy, to operate a pharmacy doing business in this state, or to operate as a wholesale drug distributor doing business in this state, or in making application for a registration to practice as a pharmacist-intern or a pharmacy technician. It includes false representations of a material fact, whether by word or conduct, by false or misleading allegations, or by concealment of that which should have been disclosed when making application, or attempting to file or filing with the board any false or forged diploma, certificate, affidavit, identification, or qualification in making application for a license or registration in this state.

b. Professional incompetency. Professional incompetency includes but is not limited to:

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of the pharmacist's practice.

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

(3) A failure by a pharmacist to exercise in a substantial respect that degree of care which is ordinarily exercised by the average pharmacist in the state of Iowa acting under the same or similar circumstances.

(4) A willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

c. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.

d. Habitual intoxication or addiction to the use of drugs. Habitual intoxication or addiction to the use of drugs includes, but is not limited to:

(1) The inability of a licensee or registrant to practice with reasonable skill and safety by reason of the excessive use of alcohol on a continuing basis.

(2) The excessive use of drugs which may impair a licensee's or registrant's ability to practice with reasonable skill or safety.

e. Conviction of a felony related to the profession or occupation of the licensee or registrant, or a conviction of a felony that would affect the licensee's or registrant's ability to practice within the licensee's or registrant's profession. A copy of the record of conviction or a plea of guilty shall be conclusive evidence.

f. Fraud in representations as to skill or ability. Fraud in representations as to skill or ability includes, but is not limited to, a pharmacist having made deceptive or untrue representations as to competency to perform professional services which the pharmacist is not qualified to perform by virtue of training or experience.

g. Use of untrue or improbable statements in advertisements.

h. Distribution of drugs for other than lawful purposes. The distribution of drugs for other than lawful purposes includes, but is not limited to, the disposition of drugs in violation of Iowa Code chapters 124, 126, and 155A.

i. Willful or repeated violations of the provisions of Iowa Code chapter 147 or Iowa Code chapter 272C. Willful or repeated violations of these Acts include, but are not limited to, a pharmacist's, pharmacist-intern's, or pharmacy technician's intentionally or repeatedly violating a lawful rule or regulation promulgated by the board of pharmacy or the state department of public health, violating a lawful order of the board in a disciplinary hearing, or violating the provisions of Title IV (Public Health) of the Code of Iowa.

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy or the distribution of controlled substances, prescription drugs, or nonprescription drugs.

k. Failure to notify the board within 30 days after a final decision entered by the licensing authority of another state, territory, or country which decision resulted in a license or registration revocation, suspension, or other disciplinary sanction.

l. Knowingly aiding, assisting, procuring, or advising another person to unlawfully practice pharmacy or to unlawfully perform the functions of a pharmacy technician or a pharmacist-intern.

m. Inability of a licensee or registrant to practice with reasonable skill and safety by reason of mental or physical impairment or chemical abuse.

n. Being adjudged mentally incompetent by a court of competent jurisdiction. Such adjudication shall automatically suspend a license or registration for the duration of the license or registration unless the board otherwise orders.

o. Submission of a false report of continuing education or failure to submit biennial reports of continuing education.

p. Failure to notify the board within 30 days after occurrence of any judgment or settlement of a malpractice court claim or action.

q. Failure to file the reports required by subrule 36.2(3) concerning acts or omissions committed by another licensee or registrant.

r. Willful or repeated malpractice.

s. Willful or gross negligence.

t. Obtaining any fee by fraud or misrepresentation.

u. Violating any of the grounds for revocation or suspension of a license or registration listed in Iowa Code sections 147.55, 155A.12, and 155A.15 or any of the rules of the board.

v. Practicing pharmacy without an active and current Iowa pharmacist license, operating a pharmacy without a current pharmacy license, operating a prescription drug wholesale facility without a current wholesale drug license, practicing as a pharmacist-intern without a current pharmacist-intern registration, or assisting a pharmacist with technical functions associated with the practice of pharmacy without a current pharmacy technician registration except as provided in rule 657—3.3(155A), introductory paragraph.

w. Attempting to circumvent the patient counseling requirements, or discouraging patients from receiving patient counseling concerning their prescription drug orders.

x. Noncompliance with a child support order or with a written agreement for payment of child support as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 252J.

y. Student loan default or noncompliance with the terms of an agreement for payment of a student loan obligation as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 261 or default on a repayment or service obligation under any federal or state educational loan or service-conditional scholarship program upon certification by the program of such a default.

z. Engaging in any conduct that subverts or attempts to subvert a board investigation.

aa. Employing or continuing to employ as a practicing pharmacist any person whose Iowa pharmacist license is not current and active, or employing or continuing to employ a person to assist a pharmacist with technical functions associated with the practice of pharmacy who is not currently registered as a pharmacy technician except as provided in rule 657—3.3(155A), introductory paragraph.

ab. Retaliatory action. Retaliating against a pharmacist, pharmacist-intern, or a pharmacy technician for making allegations of illegal or unethical activities, making required reports to the board, or cooperating with a board investigation or survey.

ac. Failing to create and maintain complete and accurate records as required by state or federal law, regulation, or rule of the board.

ad. Violating the pharmacy or drug laws or rules of another state while under the jurisdiction of that state.

ae. Having a license to practice pharmacy issued by another state canceled, revoked, or suspended for conduct substantially equivalent to any of the grounds for disciplinary action in Iowa. A copy of the record from the state taking the disciplinary action shall be conclusive evidence of the action taken by that state.

af. Failure to comply with mandatory child or dependent adult abuse reporter training requirements.

ag. Failure to timely provide to the board or a representative of the board prescription fill data or other required pharmacy or controlled substances records.

ah. Nonpayment of a state debt as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 272D.

657—36.2(155A,272C) Investigations.

36.2(1) *General.* The board may, upon receipt of a written or verbal complaint or upon its own motion pursuant to other evidence received by the board, review and investigate alleged acts or omissions that the board reasonably believes constitute cause under applicable law or administrative rules for licensee, registrant, or permittee discipline.

36.2(2) *Reporting of judgments or settlements.* Each licensee or registrant shall report to the board every adverse judgment in a malpractice action to which the pharmacy, pharmacist, pharmacist-intern, or pharmacy technician is a party, and every settlement of a claim alleging malpractice. The report must be filed within 30 days from the date of the judgment or settlement.

36.2(3) *Reporting of acts or omissions.* Each licensee or registrant having firsthand knowledge of acts or omissions set forth in subrule 36.1(4) shall report to the board within 30 days of initially acquiring the information those acts or omissions committed by another person licensed to practice pharmacy or

registered to practice as a pharmacist-intern or as a pharmacy technician. The report shall include the name and other available information identifying the licensee or registrant and the date, time, and place of the incident.

36.2(4) *Confidentiality of investigative files.* Complaint files, investigation files, and all other investigation reports and investigative information in the possession of the board or its employees or agents that relate to licensee, permittee, or registrant discipline shall be privileged and confidential pursuant to Iowa Code section 272C.6(4).

36.2(5) *Investigation of allegations.* In order to determine if probable cause exists for a disciplinary hearing, the board, the executive secretary/director, or someone designated by the executive secretary/director shall cause an investigation to be made into the allegations of the complaint. The licensee, registrant, or permittee complained of shall be given the opportunity to present to the investigator a position or defense respecting the allegations of the complaint prior to the commencement of a contested case.

36.2(6) *Investigatory subpoena powers.* The board is authorized by law to subpoena books, papers, records, and any other real evidence, whether or not privileged or confidential under law, to help determine whether a contested case proceeding (hearing) should be commenced.

36.2(7) *Investigative report.* Upon completion of the investigation, the investigator(s) shall prepare a report for the board's consideration. The report may contain the position or defense of the respondent, discuss jurisdiction, and set forth any legal arguments and authorities that appear applicable to the case.

36.2(8) *Board consideration.* The board shall review all investigations. Participation in the review shall not bar any board member from participating in any subsequent disciplinary proceeding.

a. Board action. After reviewing an investigation, the board may either institute a disciplinary proceeding by filing one or more statements of charges, send a confidential letter of education or administrative warning to the licensee, registrant or permittee, request additional investigation, or close the case without further investigation.

b. Confidential action. If the board determines that formal disciplinary action is not warranted, the board may send a confidential letter of education or administrative warning to the licensee, registrant or permittee. The purpose of a confidential letter of education or administrative warning is to alert the licensee, registrant or permittee to possible violations of Iowa law or board rules so that the licensee, registrant or permittee may address the issues. Confidential letters of education and administrative warnings do not constitute formal disciplinary action and are not public records. The board shall maintain a copy of the confidential letter of education or administrative warning in the confidential investigative file regarding the licensee, registrant or permittee. Confidential letters of education and administrative warnings may be used as evidence against a licensee, registrant or permittee in future administrative hearings.

657—36.3(147,272C) Peer review committees.

36.3(1) *Establish committee.* The board may establish and register peer review committees.

36.3(2) *Referral to committee.* The board shall determine which complaints or other matters shall be referred to a peer review committee for investigation, review, and report to the board.

36.3(3) *Services to committee.* The board may provide investigatory and related services to a peer review committee upon request.

36.3(4) *Investigation by committee.* A peer review committee may determine the method to be used in making its investigation, or that it is unable to investigate the report upon a complaint and return the complaint, together with an explanation, to the board.

36.3(5) *Confidentiality.* A peer review committee shall observe the requirements of confidentiality imposed by Iowa Code section 272C.6.

36.3(6) *Immunity from civil liability.* Members of a peer review committee shall not be liable for acts, omissions, or decisions made in connection with service on a peer review committee. However, immunity from civil liability shall not apply if the act is done with malice.

36.3(7) *Committee procedures.* A peer review committee shall submit to the board for approval the procedures to be used for review, investigation, and handling of all complaints.

657—36.4(17A,124,124B,126,147,155A,272C) Disciplinary proceedings. The proceeding for revocation, suspension, or other disciplinary sanctions against a pharmacy license, a wholesale drug license, a pharmacy technician registration, a pharmacist-intern registration, or a license to practice pharmacy, or the denial of or refusal to issue or renew a license or registration, or the suspension, denial, or revocation of a permit to handle precursor substances shall be substantially in accordance with the procedures set forth in 657—Chapter 35 and these rules, which are in addition to the procedures stated in Iowa Code sections 147.58 et seq., and 155A.16.

657—36.5(17A,124,124B,126,147,155A,272C) Notice of disciplinary hearing.

36.5(1) *Preparation of notice.* The executive secretary/director shall prepare the notice of hearing upon direction to do so by the board upon a probable cause determination.

36.5(2) *Contents.* The notice of hearing shall contain the information set forth in 657—subrule 35.5(2).

36.5(3) *Delivery.* Delivery of the notice shall constitute the commencement of the contested case proceeding, and delivery may be executed by one of the methods provided for in 657—subrule 35.5(1).

36.5(4) *Timely service – denial of renewal.* Notice of a hearing involving denial of license, permit, or registration renewal shall be served no later than 30 days before the expiration of the license, permit, or registration.

36.5(5) *Timely service – revocation or suspension.* Notice of a hearing involving revocation or suspension of a license, permit, or registration shall be served no less than 30 days before the time set for the hearing.

657—36.6(17A,124B,147,155A,272C) Informal settlement.

36.6(1) *Negotiating parties.*

a. A contested case may be resolved by informal settlement. The respondent or the board may initiate negotiation of an informal settlement.

b. The board chairperson may designate the executive secretary/director or one or more board members with authority to negotiate on behalf of the board.

36.6(2) *Waiver of notice and opportunity to be heard.* The decision to enter into informal settlement negotiations is voluntary on the part of the respondent. By entering into informal settlement negotiations, the respondent waives the right to seek disqualification of a board member pursuant to Iowa Code section 17A.17 and 657—35.9(17A) based on that board member's participation in the settlement negotiations. Upon initiation of negotiation, the assistant attorney general is authorized to discuss informal settlement with the board's designee. Consent to negotiation by the respondent also constitutes a waiver of notice and opportunity to be heard pursuant to Iowa Code section 17A.17 during informal settlement negotiation.

36.6(3) *Board approval.* All informal settlements are subject to approval of a majority of the full board. If the board fails to approve an informal settlement, it shall be of no force or effect to either party.

36.6(4) *Participation of designee.* A board member who is designated to act in negotiation of an informal settlement may review investigative material in the course of conducting the negotiation. The designated board member is not disqualified from participating in the adjudication of the contested case by virtue of reviewing the investigative material or having participated in negotiation discussions.

657—36.7(272C) Appearance. The respondent shall have the right to appear before the board in person or by attorney at the respondent's expense.

657—36.8(17A,124B,147,155A,272C) Order of proceedings. Before testimony is presented, the record shall show the identity of any board members present, the presiding hearing officer, the primary parties and their representatives, and the fact that all testimony is being recorded.

Hearings before the board generally follow the order established by this rule.

1. The presiding officer may read the specification of charges and the answer thereto, or other responsive pleading, filed by the respondent prior to the hearing.

2. The assistant attorney general representing the public interest before the board may make an opening statement.

3. Each respondent shall be offered the opportunity to make an opening statement. A respondent may elect to reserve an opening statement until just prior to the presentation of evidence by the respondent.

4. Evidence is presented on behalf of the public.

5. Evidence is presented on behalf of the respondent(s).

6. Rebuttal evidence is presented on behalf of the public.

7. Rebuttal evidence is presented on behalf of the respondent(s).

8. The parties are offered the opportunity to make closing arguments, first on behalf of the public, then on behalf of the respondent, and then on behalf of the public.

657—36.9(272C) Confidentiality. At no time prior to the release of the final decision by the board shall any portion or the whole thereof be made public or be distributed to any persons other than the parties.

657—36.10(17A,272C) Notification of decision. All parties to a proceeding hereunder shall be promptly furnished with a copy of any final decision or order either in person or by first-class mail, or by telephone if necessary to ensure that the parties learn of the decision or order first.

657—36.11(272C) Board decision. The board's decision and order to discipline a licensee, registrant, or permittee, or to revoke or suspend a license to practice pharmacy, a wholesale drug license, a license to operate a pharmacy, a registration to practice as a pharmacist-intern or as a pharmacy technician, or a permit to handle precursor substances, shall remain in force and effect until the appeal is finally determined and disposed of upon its merit unless the board grants a stay of its decision as provided for in rule 657—35.28(17A).

657—36.12(17A,272C) Publication of decisions. Final decisions of the board relating to disciplinary proceedings are public records subject to Iowa Code chapter 22, examination of public records, and may be transmitted to the appropriate professional association and a newspaper of general circulation to be selected by the board.

657—36.13(17A,124B,147,155A,272C) Reinstatement. Any person whose license to practice pharmacy or to operate a pharmacy or whose wholesale drug license or permit to handle precursor substances or whose pharmacy technician registration or pharmacist-intern registration has been revoked or suspended shall meet the following eligibility requirements for reinstatement:

36.13(1) *Prerequisites.* The individual shall satisfy all terms of the order of revocation or suspension or court proceedings as they apply to that revocation or suspension. If the order of revocation or suspension did not establish terms and conditions upon which reinstatement might occur, or if the license, registration, or permit was voluntarily surrendered, an initial application for reinstatement may not be made until one year has elapsed from the date of the board's order or the date of voluntary surrender.

36.13(2) *Pharmacist license revoked or surrendered—examinations required.* A person whose license to practice pharmacy was revoked or voluntarily surrendered must successfully pass the North American Pharmacist Licensure Examination (NAPLEX) or an equivalent examination as determined by NABP and the Multistate Pharmacy Jurisprudence Examination (MPJE), Iowa Edition.

36.13(3) *Proceedings.* The respondent shall initiate all proceedings for reinstatement by filing with the board an application for reinstatement of the license, registration, or permit. The application shall be docketed in the original case in which the license, registration, or permit was revoked, suspended, or surrendered. All proceedings upon petition for reinstatement, including all matters preliminary and ancillary thereto, shall be subject to the same rules of procedure as other cases before the board. The board and the respondent may informally settle the issue of reinstatement. The respondent may choose to have an informal reinstatement conference before the board, as provided in rule 36.14(17A,124B,147,155A,272C).

36.13(4) *Burden of proof.* An application for reinstatement shall allege facts which, if established, will be sufficient to enable the board to determine that the basis for the revocation or suspension no longer exists and that it will be in the public interest for the license, registration, or permit to be reinstated. The burden of proof to establish such facts shall be on the respondent.

36.13(5) *Order.* An order for reinstatement shall be based upon a decision that incorporates findings of facts and conclusions of law and shall be based upon the affirmative vote of a quorum of the board. This order shall be available to the public as provided in 657—Chapter 14.

657—36.14(17A,124B,147,155A,272C) Informal reinstatement conference.

36.14(1) *Request.* Upon written request of the respondent and approval by the executive secretary/director of the board, an informal reinstatement conference may be held before the board.

36.14(2) *Confidentiality.* The conference shall be open to the public except as provided in Iowa Code chapter 21 and Iowa Code section 272C.6. Material submitted to the board regarding a licensee, registrant, or permittee subject to suspension or revocation and received prior to the filing of an application for reinstatement shall be deemed to be investigatory in nature and therefore confidential. If a request for an informal settlement conference is made and approved, all material submitted by the respondent to the board for its consideration shall be deemed public records and is not confidential. Upon filing a request for an informal reinstatement conference, the respondent consents to the provision of relevant materials to board members prior to the time of the informal reinstatement conference.

36.14(3) *Disposition.* After conducting an informal reinstatement conference, the board may issue a proposed order for reinstatement, may issue a proposed order denying reinstatement, or may order a formal hearing on the application.

36.14(4) *Appeal—formal hearing.* Upon appeal of a proposed order or upon the board's order for formal hearing, application for reinstatement shall be set for formal hearing subject to the same rules of procedure as other cases before the board. By consenting to the informal settlement conference, respondent waives any objection to any board member participating in a formal hearing by virtue of the board member's participation at the informal settlement conference. All materials submitted and statements made by the respondent at the informal settlement conference shall be admissible at a subsequent formal hearing.

36.14(5) *Final order.* A proposed order resulting from an informal reinstatement conference becomes the final decision of the board without further proceedings unless there is an appeal to, or review on motion of, the board within the time provided in rule 657—35.26(17A,124B,126,147,155A,205,272C).

657—36.15(17A,124B,147,155A,272C) Voluntary surrender of a license, permit, or registration. The voluntary surrender of a license to practice pharmacy, a license to operate a pharmacy, a wholesale drug license, a permit to handle precursor substances, a pharmacy technician registration, or a pharmacist-intern registration shall be considered a revocation of license, permit, or registration. A request for reinstatement shall be handled under the terms established by rule 36.13(17A,124B,147, 155A,272C).

657—36.16(17A,124B,147,155A,272C) License, permit, or registration denial. Any request for a hearing before the board concerning the denial of a license, permit, or registration shall be submitted by the applicant in writing to the board by certified mail, return receipt requested, within 30 days of a mailing of a notice of denial of license, permit, or registration.

657—36.17(155A,272C) Order for mental or physical examination. A pharmacist, pharmacist-intern, or pharmacy technician who is licensed or registered by the board is, as a condition of licensure or registration, under a duty to submit to a mental or physical examination within a time period specified by order of the board. Such examination may be ordered upon a showing of probable cause and shall be at the expense of the pharmacist, pharmacist-intern, or pharmacy technician.

36.17(1) *Content of order.* A board order for mental or physical examination shall include the following items:

a. A description of the type of examination to which the pharmacist, pharmacist-intern, or pharmacy technician must submit.

b. The name and address of the examiner or treatment facility that the board has identified to perform the examination on the pharmacist, pharmacist-intern, or pharmacy technician.

c. The time period in which the pharmacist, pharmacist-intern, or pharmacy technician must schedule the required examination.

d. The amount of time in which the pharmacist, pharmacist-intern, or pharmacy technician is required to complete the examination.

e. A requirement that the pharmacist, pharmacist-intern, or pharmacy technician cause a report of the examination results to be provided to the board within a specified period of time.

f. A requirement that the pharmacist, pharmacist-intern, or pharmacy technician communicate with the board regarding the status of the examination.

g. A provision allowing the pharmacist, pharmacist-intern, or pharmacy technician to request additional time to schedule or complete the examination or to request that the board approve an alternative examiner or treatment facility. The board shall, in its sole discretion, determine whether to grant such a request.

36.17(2) *Objection to order.* A licensee or registrant who is the subject of a board order and who objects to the order may file a request for hearing. The request for hearing shall specifically identify the factual and legal issues upon which the licensee or registrant bases the objection. The hearing shall be considered a contested case proceeding and shall be governed by the provisions of 657—Chapter 35. A contested case involving an objection to an examination order will be captioned in the name of Jane or John Doe in order to maintain the licensee's or registrant's confidentiality.

36.17(3) *Closed hearing.* Any hearing on an objection to the board order shall be closed pursuant to Iowa Code section 272C.6(4).

36.17(4) *Order and reports—confidential.* An examination order and any subsequent examination reports issued in the course of a board investigation are confidential investigative information pursuant to Iowa Code section 272C.6(4).

657—36.18(272C) Disciplinary hearings—fees and costs.

36.18(1) *Definitions.* As used in this chapter in relation to a formal disciplinary action filed by the board against a licensee or registrant:

"Deposition" means the testimony of a person pursuant to subpoena or at the request of the state of Iowa taken in a setting other than a hearing.

"Expenses" means costs incurred by persons appearing pursuant to subpoena or at the request of the state of Iowa for purposes of providing testimony on the part of the state of Iowa in a hearing or other official proceeding and shall include mileage reimbursement at the rate specified in Iowa Code section 70A.9 or, if commercial air or ground transportation is used, the actual cost of transportation to and from the proceeding. Also included are actual costs incurred for meals and necessary lodging.

"Medical examination fees" means actual costs incurred by the board in a physical, mental, chemical abuse, or other impairment-related examination or evaluation of a licensee or registrant when the examination or evaluation is conducted pursuant to an order of the board.

"Transcript" means a printed verbatim reproduction of everything said on the record during a hearing or other official proceeding.

"Witness fees" means compensation paid by the board to persons appearing pursuant to subpoena or at the request of the state of Iowa, for purposes of providing testimony on the part of the state of Iowa. For the purposes of this rule, compensation shall be the same as outlined in Iowa Code section 622.69 or 622.72 as the case may be.

36.18(2) *Hearing fee and recoverable costs.* The board may charge a fee not to exceed $75 for conducting a disciplinary hearing that results in disciplinary action taken by the board against the license

or registration. In addition to the fee, the board may recover from the licensee or registrant costs for the following procedures and personnel:

a. Transcript.

b. Witness fees and expenses.

c. Depositions.

d. Medical examination fees incurred relating to a person licensed or registered under Iowa Code chapter 147 or 169.

36.18(3) *Fees, costs are part of disciplinary order.* Fees and costs assessed by the board pursuant to subrule 36.18(2) shall be calculated by the board's executive secretary/director and shall be entered as part of the board's final disciplinary order. The board's final disciplinary order shall specify the time period in which the licensee or registrant shall pay the assessed fees and costs.

36.18(4) *Board treatment of collected fees, costs.* Fees and costs collected by the board pursuant to subrule 36.18(2) shall be allocated to the expenditure category of the board in which the hearing costs were incurred. The fees and costs shall be considered repayment receipts as defined in Iowa Code section 8.2.

36.18(5) *Failure to pay assessed fees, costs.* Failure of a licensee or registrant to pay the fees and costs assessed herein within the time period specified in the board's final disciplinary order shall constitute a violation of a lawful order of the board.

These rules are intended to implement Iowa Code sections 17A.10 to 17A.23, 124.301, 124.304, 124B.12, 126.16 to 126.18, 155A.6, 155A.12, 155A.13, 155A.13A, 155A.15 to 155A.18, 155A.25, 205.11, 272C.3 to 272C.6, 272C.9, and 272C.10.

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CHAPTER 37
IOWA PRESCRIPTION MONITORING PROGRAM

657—37.1(124) Purpose. These rules establish a prescription monitoring program that compiles a central database of reportable prescriptions dispensed to patients in Iowa. An authorized health care practitioner may, but is not required to, access prescription monitoring program (PMP) information regarding the practitioner's patient to assist in determining appropriate treatment options and to improve the quality of patient care. The PMP is intended to provide a health care practitioner with a resource for information regarding a patient's use of controlled substances. This database will assist the practitioner in identifying any potential diversion, misuse, or abuse of controlled substances without impeding the appropriate medical use of controlled substances.
[**ARC 7903B**, IAB 7/1/09, effective 8/5/09]

657—37.2(124) Definitions. As used in this chapter:

"Board" means the Iowa board of pharmacy.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through V set forth in Iowa Code chapter 124, division II.

"Council" means the PMP advisory council established pursuant to Iowa Code section 124.555 to provide oversight and to co-manage PMP activities with the board.

"Database information" or *"PMP information"* means information submitted to and maintained by the PMP database.

"DEA number" means the registration number issued to an individual or pharmacy by the U.S. Department of Justice, Drug Enforcement Administration authorizing the individual or pharmacy to engage in the prescribing, dispensing, distributing, or procuring of a controlled substance.

"Dispenser" means a person who delivers to the ultimate user a substance required to be reported to the PMP database. "Dispenser" does not include a person exempt from reporting pursuant to subrule 37.3(1).

"National drug code" or *"NDC number"* means the universal product identifier used in the United States to identify a specific human drug product.

"Patient" means the person or animal that is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

"Patient's agent" means a person legally authorized to make health care decisions or gain access to health care records on behalf of the patient for purposes of directing the patient's care.

"Patients rights committee" or *"committee"* means the physician and pharmacist members of the council responsible for monitoring and ensuring protection and preservation of patients' rights as provided in Iowa Code section 124.555(3)*"e."*

"PMP administrator" means the board staff person or persons designated to manage the PMP under the direction and oversight of the board and the council.

"Practitioner" means a prescriber or a pharmacist.

"Prescriber" means a licensed health care professional with the authority to prescribe prescription drugs including controlled substances.

"Prescription monitoring program" or *"PMP"* means the program established pursuant to these rules for the collection and maintenance of PMP information and for the provision of PMP information to authorized individuals, including health care providers, for use in treatment of their patients.

"Prescription monitoring program database" or *"PMP database"* means a centralized database of reportable controlled substance prescriptions dispensed to patients and includes data access logs, security tracking information, and records of each individual who requests PMP information.

"Reportable prescription" means the record of a Schedule II, III, or IV controlled substance dispensed by a pharmacy to a patient pursuant to a prescriber-authorized prescription. "Reportable prescription" does not include those records excluded in subrule 37.3(1).

"Schedule II, III, and IV controlled substances" means those substances that are identified and listed as Schedule II, III, or IV substances in Iowa Code sections 124.205 through 124.210 or in the federal Controlled Substances Act (21 U.S.C. Section 812).
[**ARC 7903B**, IAB 7/1/09, effective 8/5/09]

657—37.3(124) Requirements for the PMP. Each dispenser, unless identified as exempt from reporting pursuant to subrule 37.3(1), shall submit to the PMP administrator a record of each reportable prescription dispensed during a reporting period.

37.3(1) *Exemptions.* The dispensing of a controlled substance as described in this subrule shall not be considered a reportable prescription. A dispenser engaged in the distribution of controlled substances solely pursuant to one or more of the practices identified in paragraphs *"a"* or *"b"* of this subrule shall so notify the PMP administrator and shall be exempt from reporting to the PMP.

a. A licensed hospital pharmacy shall not be required to report the dispensing of a controlled substance for the purposes of inpatient hospital care, the dispensing of a prescription for a starter supply of a controlled substance at the time of a patient's discharge from such a facility, or the dispensing of a prescription for a controlled substance in a quantity adequate to treat the patient for a maximum of 72 hours.

b. A licensed pharmacy shall not be required to report the dispensing of a controlled substance for a patient residing in a long-term care facility or for a patient residing in an inpatient hospice facility.

c. A prescriber or other authorized person who administers or dispenses a controlled substance, including samples of a controlled substance, for the purposes of outpatient care shall not be required to report such administration or dispensing. This exception shall not apply to a pharmacist who administers a controlled substance, as directed by the prescriber, pursuant to a prescription.

d. A wholesale distributor of a controlled substance shall not be required to report the wholesale distribution of such a substance.

37.3(2) *Data elements.* The information submitted for each prescription shall include, at a minimum, the following items:

a. Dispenser DEA number.
b. Date the prescription is filled.
c. Prescription number.
d. Indication as to whether the prescription is new or a refill.
e. NDC number for the drug dispensed.
f. Quantity of the drug dispensed.
g. Number of days of drug therapy provided by the drug as dispensed.
h. Patient name.
i. Patient address including street address, city, state, and ZIP code.
j. Patient date of birth.
k. Patient gender.
l. Prescriber DEA number.
m. Date the prescription was issued by the prescriber.
n. Method of payment as either third-party payer or patient cash payment.

37.3(3) *Reporting periods.* A record of each reportable prescription dispensed shall be submitted by each dispenser pursuant to the following schedule. Records may be submitted with greater frequency than required by this schedule. This schedule defines minimum report frequency.

a. Records of reportable prescriptions dispensed between the first and the fifteenth day of a month shall be submitted no later than the twenty-fifth day of the month.

b. Records of reportable prescriptions dispensed between the sixteenth and the last day of a month shall be submitted no later than the tenth day of the following month.

37.3(4) *Transmission methods.* Prescription information shall be transmitted using one of the following methods:

a. Data upload to a reporting Web site via a secure Internet connection. The PMP administrator will provide dispensers with initial secure login and password information. Dispensers will be required to register on the reporting Web site prior to initial data upload.

b. Electronic media including CD-ROM, DVD, or diskette, accompanied by a transmittal form identifying the dispenser submitting the electronic media, the number of prescription records included on the media, and the individual submitting the media.

c. If a dispenser does not have an automated record-keeping system capable of producing an electronic report as provided in this rule, the dispenser may submit prescription information on the industry standard universal claim form. The dispenser may complete and submit the claim form on the reporting Web site or, if the dispenser does not have Internet access, the completed paper claim form may be submitted.

d. Chain pharmacies and pharmacies under shared ownership may submit combined data transmissions on behalf of all facilities by utilizing the secure FTP procedure.

37.3(5) *Zero reports.* If a dispenser has not been identified as exempt from reporting to the PMP and the dispenser did not dispense any reportable prescriptions during a reporting period, the dispenser shall submit a zero report via the established reporting Web site. If such a dispenser does not have Internet access, the dispenser shall notify the PMP administrator via mail or facsimile transmission that the dispenser did not dispense any reportable prescriptions during the reporting period. The schedule identified in subrule 37.3(3) shall determine timely submission of zero reports.

[**ARC 7903B**, IAB 7/1/09, effective 8/5/09]

657—37.4(124) Access to database information. Prescription information submitted to the board for inclusion in the PMP database shall be privileged and strictly confidential and not subject to public or open records laws. All information contained in the PMP database, including records of requests for PMP information, shall be privileged and strictly confidential and not subject to public or open records laws. The board, council, and PMP administrator shall maintain procedures to ensure the privacy and confidentiality of patients, prescribers, dispensers, practitioners, and patient information collected, recorded, transmitted, and maintained in the PMP database and to ensure that program information is not disclosed to persons except as provided in this rule.

37.4(1) *Prescribers and pharmacists.* A health care practitioner authorized to prescribe or dispense controlled substances may obtain PMP information regarding the practitioner's patient, or a patient seeking treatment from the practitioner, for the purpose of providing patient health care.

a. Prior to being granted access to PMP information, a practitioner shall submit a request for registration and program access. A practitioner with Internet access may register via a secure Web site established by the board for that purpose. A practitioner without Internet access shall submit a written registration request on a form provided by the PMP administrator. The PMP administrator shall take reasonable steps to verify the identity of a practitioner and to verify a practitioner's credentials prior to providing a practitioner with a secure login and initial password. Except in an emergency when the patient would be placed in greater jeopardy by restricting PMP information access to the practitioner, a registered practitioner shall not share the practitioner's secure login and password information and shall not delegate PMP information access to another health care practitioner or to the practitioner's agent.

b. A practitioner with Internet access may submit a request for PMP information via a secure Web site established by the board for that purpose. The requested information shall be provided to the requesting practitioner in a format established by the board and shall be delivered via the secure Web site.

c. A practitioner without Internet access may submit to the PMP administrator a written request for PMP information via mail or facsimile transmission. The written request shall be in a format established by the board and shall be signed by the requesting practitioner. Prior to processing a written request for PMP information, the PMP administrator shall take reasonable steps to verify the request, which may include but not be limited to a telephone call to the practitioner at a telephone number known to be the number for the practitioner's practice.

d. A practitioner who requests and receives PMP information consistent with the requirements and intent of these rules may provide that information to another practitioner who is involved in the care of the patient who is the subject of the information. Information from the PMP database remains privileged and strictly confidential. Such disclosures among practitioners shall be consistent with these rules and federal and state laws regarding the confidentiality of patient information. The information shall be used for medical or pharmaceutical care purposes.

37.4(2) *Regulatory agencies and boards.* Professional licensing boards and regulatory agencies that supervise or regulate a health care practitioner or that provide payment for health care services shall be able to access information from the PMP database only pursuant to an order, subpoena, or other means of legal compulsion relating to a specific investigation of a specific individual and supported by a determination of probable cause.

a. A director of a licensing board with jurisdiction over a practitioner, or the director's designee, who seeks access to PMP information for an investigation shall submit to the PMP administrator in a format established by the board a written request via mail, facsimile, or personal delivery. The request shall be signed by the director or the director's designee and shall be accompanied by an order, subpoena, or other form of legal compulsion establishing that the request is supported by a determination of probable cause.

b. A director of a regulatory agency with jurisdiction over a practitioner or with jurisdiction over a person receiving health care services pursuant to one or more programs provided by the agency, or the director's designee, who seeks access to PMP information for an investigation shall submit to the PMP administrator in a format established by the board a written request via mail, facsimile, or personal delivery. The request shall be signed by the director or the director's designee and shall be accompanied by an order, subpoena, or other form of legal compulsion establishing that the request is supported by a determination of probable cause.

37.4(3) *Law enforcement agencies.* Local, state, and federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of any state or federal law relating to controlled substances shall be able to access information from the PMP database by order, subpoena, or other means of legal compulsion relating to a specific investigation of a specific individual and supported by a determination of probable cause. A law enforcement officer shall submit to the PMP administrator in a format established by the board a written request via mail, facsimile, or personal delivery. The request shall be signed by the requesting officer or the officer's superior. The request shall be accompanied by an order, subpoena, or warrant issued by a court or legal authority that requires a determination of probable cause and shall be processed by the PMP administrator. A report identifying PMP information relating to the specific individual identified by the order, subpoena, or warrant may be delivered to the law enforcement officer via mail or alternate secure delivery.

37.4(4) *Patients.* A patient or the patient's agent may request and receive PMP information regarding prescriptions reported to have been dispensed to the patient.

a. A patient may submit a signed, written request for records of the patient's prescriptions dispensed during a specified period of time. The request shall identify the patient by name, including any aliases used by the patient, and shall include the patient's date of birth and gender. The request shall also include any address where the patient resided during the time period of the request and the patient's current address and daytime telephone number. A patient may personally deliver the request to the PMP administrator or authorized staff member at the offices of the board located at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. The patient will be required to present current government-issued photo identification at the time of delivery of the request. A copy of the patient's identification shall be maintained in the records of the PMP.

b. A patient who is unable to personally deliver the request to the board offices may submit a request via mail or commercial delivery service. The request shall comply with all provisions of paragraph *"a"* above, and the signature of the requesting patient shall be witnessed and the patient's identity shall be attested to by a currently registered notary public. In addition to the notary's signature and assurance of the patient's identity, the notary shall certify a copy of the patient's government-issued

photo identification and that certified copy shall be submitted with the written request. The request shall be submitted to the Iowa Board of Pharmacy at the address identified in paragraph *"a."*

c. In the case of a patient whose health care decisions have been legally transferred to the patient's agent, the patient's agent may submit a request on behalf of the patient pursuant to the appropriate procedure in paragraph *"a"* or *"b."* In addition to the patient's information, the patient's agent shall be identified by name, current address, and telephone number. In lieu of the patient's signature and identification, the patient's agent shall sign the request and the government-issued photo identification shall identify the patient's agent. The patient's agent shall include a certified copy of the legal document that transferred control over decisions regarding the patient's health care to the patient's agent.

37.4(5) *Court orders and subpoenas.* The PMP administrator shall provide PMP information in response to court orders and county attorney or other subpoenas issued by a court upon a determination of probable cause.

37.4(6) *Statistical data.* The PMP administrator, following review and approval by the patients rights committee, may provide summary, statistical, or aggregate data to public or private entities for statistical, research, or educational purposes. Prior to the release of any such data, the PMP administrator shall remove any information that could be used to identify an individual patient, prescriber, dispenser, practitioner, or other person who is the subject of the PMP information or data.

37.4(7) *PMP administrator access.* Other than technical, error, and administrative function reports needed by PMP support staff to determine that records are received and maintained in good order, any other reports concerning the information received from dispensers shall only be prepared at the direction of the board, the council, or the PMP administrator. The board and the council may compile statistical reports from PMP information for use in determining the advisability of continuing the PMP and for use in preparing required reports to the governor and the legislature. The reports shall not include information that would identify any patient, prescriber, dispenser, practitioner, or other person who is the subject of the PMP information or data.

[**ARC 7903B**, IAB 7/1/09, effective 8/5/09]

657—37.5(124) Fees. The board may charge a fee and recover costs incurred for the provision of PMP information, including statistical data, except that no fees or costs shall be assessed to a dispenser for reporting to the PMP or to a practitioner for querying the PMP regarding a practitioner's patient. Any fees or costs assessed by the board shall be considered repayment receipts as defined in Iowa Code section 8.2.

[**ARC 7903B**, IAB 7/1/09, effective 8/5/09]

657—37.6(124) PMP information retained. All dispenser records of prescriptions reported to the PMP shall be retained by the PMP for a period of four years following the date of the record. All records of access to or query of PMP information shall be retained by the PMP for a period of four years following the date of the record. At least semiannually, all PMP information identified as exceeding that four-year period shall be deleted from the PMP and discarded in a manner to maintain the confidentiality of the PMP information and data. Statistical data and reports from which all personally identifiable information has been removed or which do not contain personally identifiable information as provided in subrules 37.4(6) and 37.4(7) may be retained by the PMP for historical purposes.

[**ARC 7903B**, IAB 7/1/09, effective 8/5/09]

657—37.7(124) Information errors. Any person who believes that PMP information about that person is false or in error shall submit a written statement to the PMP administrator. The statement shall identify the information the person believes to be false or in error and the reason the individual believes the information to be false or in error. The PMP administrator may examine the information identified in the statement and may request the assistance of the board's compliance staff to determine whether or not the PMP information is accurate. Prior to initiating any action to correct, delete, or amend any PMP information, the PMP administrator shall submit the statement and the resulting report to the patients rights committee for review and approval of the recommended action. If correction, deletion, or amendment of any PMP information is authorized, that action shall be accomplished by the PMP

administrator within 72 hours of the committee's decision. The PMP administrator shall respond, in writing, to the person who submitted the statement charging that the PMP information was false or in error. The response shall identify the action approved by the committee.
[**ARC 7903B**, IAB 7/1/09, effective 8/5/09]

657—37.8(124) Dispenser and practitioner records. Nothing in these rules shall apply to records created or maintained in the regular course of business of a pharmacy or health care practitioner. All information, documents, or records otherwise available from pharmacies or health care practitioners shall not be construed as immune from discovery or use in any civil proceedings merely because the information contained in those records was reported to the PMP in accordance with these rules.
[**ARC 7903B**, IAB 7/1/09, effective 8/5/09]

657—37.9(124) Prohibited acts. The PMP administrator shall report to a dispenser's or a practitioner's professional licensing board any known violation of the confidentiality provisions or the reporting requirements of the law and these rules for which the dispenser or practitioner is subject to disciplinary action.

37.9(1) *Confidentiality.* A pharmacy or a practitioner who knowingly fails to comply with the confidentiality provisions of the law or these rules or who delegates PMP information access to another individual, except in an emergency situation as provided in paragraph 37.4(1)*"a,"* is subject to disciplinary action by the appropriate professional licensing board. The PMP administrator or a member of the program staff who knowingly fails to comply with the confidentiality provisions of the law or these rules is subject to disciplinary action by the board.

37.9(2) *Dispenser reporting.* A dispenser or a pharmacist who fails to comply with the reporting requirements of the law or these rules may be subject to disciplinary action by the board.
[**ARC 7903B**, IAB 7/1/09, effective 8/5/09]

These rules are intended to implement Iowa Code sections 124.551 to 124.558 as amended by 2009 Iowa Acts, House file 122.

[Filed ARC 7903B (Notice ARC 7676B, IAB 4/8/09), IAB 7/1/09, effective 8/5/09]