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 and pharmacy support persons, the distribution of prescription drugs and devices, and the education and training of pharmacists.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—1.2(17A,147,155A,272C) Description and organization of board. The board is comprised of five pharmacist members, one certified pharmacy technician member, and two representatives of the general public, all appointed by the governor. An administrative staff headed by a public health director-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, 124B, 126, 147, 155A, 205, and 272C.

[**ARC 3857C**, IAB 6/20/18, effective 7/25/18; **ARC 4188C**, IAB 12/19/18, effective 1/23/19; **ARC 5348C**, IAB 12/30/20, effective 2/3/21]

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, wholesale distributors, limited distributors, outsourcing facilities, and third-party logistics providers 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.6A, 155A.6B, 155A.12, 155A.13, 155A.13A, 155A.15, 155A.17, 155A.17A, and 155A.42 as appropriate.
10. Registering pharmacy support persons assisting in the nontechnical functions of the practice of pharmacy pursuant to the authority of Iowa Code chapter 155A.
11. Registering pharmacists in charge of nonresident pharmacies pursuant to the authority of Iowa Code chapter 155A.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 4188C**, IAB 12/19/18, effective 1/23/19]

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 website at pharmacy.iowa.gov.
[**ARC 4188C**, IAB 12/19/18, effective 1/23/19]

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 website at pharmacy.iowa.gov. 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 website.

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 director 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.
[**ARC 4188C**, IAB 12/19/18, effective 1/23/19]

657—1.6(124,147,155A) Fee for returned check. A nonrefundable 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 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.
[**ARC 4188C**, IAB 12/19/18, effective 1/23/19]

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.

657—1.8(155A) Alternate board members. The board may have a pool of up to seven alternate members, to include individuals who may or may not be licensed to practice under Iowa Code chapter 155A, to substitute for board members unable to participate in a contested case hearing. Utilization of such alternate board members shall be in compliance with Iowa Code section 155A.2A. Whenever there are fewer than seven individuals serving in the pool of alternate board members, the executive director may present to the board for approval a list of individuals eligible to serve in the pool. The board may select individuals to serve as alternate board members, subject to approval by the governor. The term of each alternate board member shall begin on the first day of the month following approval by the governor and shall last for three years or until the alternate board member resigns, whichever occurs first. An alternate board member may serve no more than nine years as an alternate board

member. Upon approval by the governor of an alternate board member, the executive director may select that alternate board member to hear a contested case when a sufficient number of board members are unavailable to hear a contested case for any reason.
[**ARC 4188C**, IAB 12/19/18, effective 1/23/19]

These rules are intended to implement Iowa Code sections 17A.3, 21.3 through 21.5, 124.301, 124B.11, 147.14, 147.76, 147.96, 155A.2, 155A.2A, 155A.6, 155A.6A, 155A.6B, 155A.11, 155A.13, 155A.13A, 155A.13C, 155A.14, 155A.15, 155A.17, 155A.17A, 155A.42, 272C.3, and 272C.4.

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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) Purpose and scope. The purpose of this chapter is to set the minimum standards and application process for obtaining and maintaining pharmacist licensure in this state. The rules shall apply to pharmacists who seek or hold pharmacist licensure in Iowa.
[**ARC 4579C**, IAB 7/31/19, effective 9/4/19]

657—2.2(147,155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Board" means the board of pharmacy.

"Continuing pharmacy education" or *"CPE"* means a structured educational activity that is applicable to the practice of pharmacy, that promotes problem solving and critical thinking, and that is designed or intended to support the continuing development of pharmacists to maintain and enhance their competence in the practice of pharmacy.

"Continuing professional development" or *"CPD"* means a self-directed, ongoing, systematic, and outcomes-focused approach to learning and professional development including active participation in learning activities that assist a pharmacist in developing and maintaining continuing competence in the practice of pharmacy, enhancing the pharmacist's professional practice, and supporting achievement of the pharmacist's career goals.

"CPE monitor" means the program administered by NABP to collect and store CPE data for pharmacy professionals.

"NABP" means the National Association of Boards of Pharmacy.

"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.
[**ARC 4579C**, IAB 7/31/19, effective 9/4/19]

657—2.3(147,155A) License and criminal history record check required.

2.3(1) *License required.* Prior to engaging in the practice of pharmacy in Iowa, a pharmacist shall have an active Iowa pharmacist license.

2.3(2) *Criminal history record check required.* Upon receipt of an application for initial licensure pursuant to subrule 2.3(1) or for reactivation pursuant to rule 657—2.11(147,155A), the board shall provide a fingerprint packet to the applicant, who shall submit to the board the completed fingerprint packet and a signed waiver form to facilitate a national criminal history background check of the applicant. The cost of the evaluation of the fingerprint packet and the Iowa division of criminal investigation and United States Federal Bureau of Investigation criminal history background checks will be assessed to the applicant.
[**ARC 4579C**, IAB 7/31/19, effective 9/4/19; **ARC 5750C**, IAB 7/14/21, effective 8/18/21]

657—2.4(147,155A) Licensure by examination. The board, in conjunction with NABP, shall provide for the administration of pharmacist licensure examinations.

2.4(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.

2.4(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 from this deadline pursuant to the procedures and requirements of 657—Chapter 34.

2.4(3) *Examination results.* Examination scores and original license certificates shall be provided as soon after the examinations as possible.
[**ARC 4579C**, IAB 7/31/19, effective 9/4/19; **ARC 5348C**, IAB 12/30/20, effective 2/3/21]

657—2.5(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 additionally apply for eligibility to take the NAPLEX and the Multistate Pharmacy Jurisprudence Examination (MPJE), Iowa Edition, at nabp.pharmacy/programs.

2.5(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 or individual tax identification number (ITIN); 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. If the applicant provides an ITIN in lieu of a social security number, the applicant shall also provide acceptable proof of lawful presence. 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.

2.5(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.

2.5(3) *Fee.* The nonrefundable fee for examination shall consist of the biennial license fee, a processing fee, and an examination registration fee.

a. The biennial license fee shall be $180, and the processing fee shall be $72. The nonrefundable biennial license fee and processing fee shall be submitted to the board with the application for licensure by examination.

b. The examination registration fee shall be an amount determined by NABP and submitted pursuant to NABP direction at nabp.pharmacy/programs when submitting an application for eligibility to take the NAPLEX; the MPJE, Iowa Edition; or both.

2.5(4) *College graduation certification.* Each applicant, with the exception of a foreign pharmacy graduate who shall comply with rule 657—2.10(155A), shall furnish a certificate from a recognized college of pharmacy stating that the applicant has successfully graduated from a college of pharmacy with either a bachelor of science degree in pharmacy or a doctor of pharmacy 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 Accreditation Council for Pharmacy Education and appears on the list of accredited colleges of pharmacy published by the council as of July 1 of each year.

2.5(5) *Foreign pharmacy graduates.* In addition to the requirements of this rule, except as provided in subrule 2.5(4), an 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 obtain certification by the Foreign Pharmacy Graduate Examination Committee (FPGEC) pursuant to rule 657—2.10(155A).
[**ARC 3636C**, IAB 2/14/18, effective 3/21/18; **ARC 4579C**, IAB 7/31/19, effective 9/4/19]

657—2.6(155A) Internship requirements. Each applicant, except for an applicant for license transfer, 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.
[**ARC 4579C**, IAB 7/31/19, effective 9/4/19]

657—2.7(147) Reexamination applications and fees. A candidate who fails to pass either the NAPLEX or the MPJE, Iowa Edition, once shall be allowed to schedule a time to retake the examination as provided in this rule. To ensure the integrity of the examinations, no waiver of the specified waiting period between reexaminations will be granted.

2.7(1) *NAPLEX.* A candidate who fails to pass the NAPLEX once shall be allowed to schedule a time to retake the examination no less than 45 days following administration of the failed examination. The candidate may be approved to retake the NAPLEX no more than three times in a 12-month period.

2.7(2) *MPJE, Iowa Edition.* 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.

2.7(3) *Reexamination after two or more attempts.* 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.

2.7(4) *Applications and fees.* Each applicant for reexamination shall file an application on forms provided by the board. A nonrefundable processing fee of $36 will be charged for each NAPLEX or MPJE, Iowa Edition, reexamination and shall be paid to the board. In addition, the applicant shall complete the NABP application process for reexamination and pay the required fee for reexamination as determined by NABP at nabp.pharmacy/programs.

[**ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 3099C**, IAB 6/7/17, effective 7/12/17; **ARC 4579C**, IAB 7/31/19, effective 9/4/19; **ARC 5348C**, IAB 12/30/20, effective 2/3/21]

657—2.8(155A) Licensure by score transfer. 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) *Application for score transfer.* To participate in the NABP score transfer program, an applicant shall complete all required application requirements and submit required fees as determined by NABP at nabp.pharmacy/programs.

2.8(2) *Requirements and deadline.* Applicants for licensure by score transfer shall meet the requirements established in rules 657—2.4(147,155A) through 657—2.6(155A) within 12 months of the date of score transfer.

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 paragraph 2.5(3)*"a."*

[**ARC 4579C**, IAB 7/31/19, effective 9/4/19]

657—2.9(147,155A) Licensure by license transfer. An applicant for license transfer must be a pharmacist licensed in a state or territory of the United States, and the license upon which the transfer is based must be in good standing at the time of the application and license transfer. All candidates shall take and pass the MPJE, Iowa Edition, as provided in subrule 2.4(1). Any candidate who fails to pass the examination shall be eligible for reexamination as provided in rule 657—2.7(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. *Applications for license transfer.* Each applicant for license transfer to Iowa shall complete the online application and pay the required fee as determined by NABP at nabp.pharmacy/programs and submit the board's online application and pay the required nonrefundable fee at pharmacy.iowa.gov.

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 application for license transfer that is prepared by NABP and electronically submitted to the board pursuant to the NABP license transfer program. A foreign pharmacy graduate shall submit certification from the FPGEC as provided in subrule 2.10(1).

2.9(3) *MPJE required.* An applicant shall also successfully pass the MPJE, Iowa Edition, as provided in subrule 2.4(1).

2.9(4) *Fees.* The nonrefundable fee for license transfer shall consist of the biennial license fee of $180 and a processing fee of $90.

2.9(5) *Timeliness.* An application for license transfer is valid for 12 months following the date of issuance by NABP. An applicant for license transfer shall complete, within that one-year period, all licensure requirements established by this rule.
[**ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 1031C**, IAB 9/18/13, effective 10/23/13; **ARC 4579C**, IAB 7/31/19, effective 9/4/19; **ARC 5750C**, IAB 7/14/21, effective 8/18/21]

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 FPGEC. Each applicant shall have successfully passed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE) given by the FPGEC established by NABP. The FPGEE is hereby recognized and approved by the board. Each applicant shall also demonstrate proficiency in basic English language skills by passing the Internet Based Test of English as a Foreign Language (TOEFL iBT) given by the FPGEC established by NABP. The TOEFL iBT is hereby recognized and approved by the board. Certification by the FPGEC shall be evidence of the applicant's successfully passing the FPGEE and TOEFL iBT, and certification is a prerequisite to taking the licensure examinations required in subrule 2.4(1).

2.10(2) *Internship.* A foreign pharmacy graduate applicant shall also be required to obtain internship experience in one or more board-licensed pharmacies as provided in rule 657—4.7(155A). Internship requirements shall, in all other aspects, meet the requirements established in 657—Chapter 4.
[**ARC 4579C**, IAB 7/31/19, effective 9/4/19]

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 payment of a nonrefundable fee of $180.

2.11(1) *Late renewal penalty.* Failure to renew the license before July 1 following expiration shall require payment of the nonrefundable renewal fee and a nonrefundable penalty fee of $180. Failure to renew the license before August 1 following expiration shall require payment of the nonrefundable renewal fee and a nonrefundable penalty fee of $270. Failure to renew the license before September 1 following expiration shall require payment of the nonrefundable renewal fee and a nonrefundable penalty fee of $360. Failure to renew the license before October 1 following expiration may require an appearance before the board and shall require payment of a nonrefundable renewal fee of $630. The provisions of Iowa Code section 147.11 requiring reactivation shall apply to a license that is not renewed before November 1 following expiration and shall include completion of a criminal history background check pursuant to subrule 2.3(2).

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 renews the delinquent license. Renewal of a delinquent license shall include submission of a completed application and appropriate nonrefundable 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 36.6(22).
[**ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 4579C**, IAB 7/31/19, effective 9/4/19; **ARC 5750C**, IAB 7/14/21, effective 8/18/21]

657—2.12(272C) Continuing education requirements. Pharmacists shall complete continuing education for license renewal pursuant to the requirements of this rule, except as provided in subrule 2.12(6) or rule 657—2.17(272C). Nothing in these rules precludes the board from requiring an applicant for license renewal or reactivation to submit to a relicensure examination.

2.12(1) *Continuing pharmacy education (CPE) required.* A pharmacist shall complete no less than 30 hours of CPE during each renewal period except as provided in subrule 2.12(6) or rule 657—2.17(272C).

a. A pharmacist who fails to complete the required CPE hours within the renewal period shall be required to complete one and one-half times the number of delinquent CPE hours prior to reactivation of the license.

b. CPE hours that are used to satisfy the CPE requirement for one renewal period shall not be used to satisfy the requirement for a subsequent renewal period.

c. Failure to receive a license renewal application or notice of license renewal shall not relieve the pharmacist of the responsibility of meeting CPE requirements.

2.12(2) *CPE activity completion.*

a. *ACPE provider activity.* CPE activities that carry the seal of an Accreditation Council for Pharmacy Education (ACPE)-accredited provider will automatically qualify for CPE credit. Successful completion and record of CPE activities in CPE Monitor is mandated in order for a pharmacist to receive credit for ACPE-accredited provider CPE activities.

b. *Non-ACPE provider activity.* A maximum of 13 CPE hours of the total 30 CPE hours required pursuant to subrule 2.12(4) may be obtained through completion of non-ACPE provider activities if such activities are provided by an accredited health-professional continuing education provider, such as a continuing medical education (CME) provider, and if the activity content directly relates to the pharmacist's professional practice. Non-ACPE provider activity completion shall be recorded, evaluated, and reported pursuant to the provisions of rule 657—2.17(272C) regarding continuing professional development.

(1) The pharmacist is responsible for ensuring that the activity content directly relates to the pharmacist's professional practice.

(2) If one or more non-ACPE provider activities are intended to fulfill the requirement in paragraph 2.12(4)*"c,"* the pharmacist is responsible for ensuring the activity content relates to patient or medication safety.

(3) If the non-ACPE provider is not able to transmit the activity record to CPE Monitor, the provider shall provide to the pharmacist a statement of credit that indicates the pharmacist's participation in and successful completion of the continuing education activity. The statement of credit shall include all information identified in subrule 2.12(3), except for the pharmacist's CPE Monitor e-profile identification number.

2.12(3) *CPE activity record of credit.* An ACPE-accredited provider will be required to transmit to CPE Monitor information regarding an individual pharmacist's participation in and successful completion of a CPE activity. The record shall be accessible to the board and shall include the following information:

a. Pharmacist's full name and CPE Monitor e-profile identification number.

b. Number of contact hours or CEUs awarded for activity completion.

c. Date of live activity or date of completion of home study activity.

d. Name of accredited provider.

e. Activity title and universal activity number.

2.12(4) *CPE activity topics.* Each pharmacist is required to obtain CPE by completing activities in the topics specified in this subrule.

a. *Drug therapy.* A minimum of 15 CPE hours of the required 30 CPE hours shall be in ACPE-accredited provider activities dealing with drug therapy. Activities qualifying for the drug therapy requirement will include the ACPE topic designator "01" or "02" followed by the letter "P" at the end of the universal activity number.

b. *Pharmacy law.* A minimum of 2 CPE hours of the required 30 CPE hours shall be in ACPE-accredited provider activities dealing with pharmacy law. Activities qualifying for the pharmacy law requirement will include the ACPE topic designator "03" followed by the letter "P" at the end of the universal activity number.

c. *Patient or medication safety.* A minimum of 2 CPE hours of the required 30 CPE hours shall be in activities dealing with patient or medication safety. Activities completed to fulfill this requirement may be ACPE-accredited provider activities, in which case the universal activity number will end with the

ACPE topic designator "05" followed by the letter "P." A pharmacist may complete non-ACPE provider activities as provided in paragraph 2.12(2)*"b"* to fulfill this topic requirement.

d. Immunization. If the pharmacist is engaged in the administration of immunizations during the renewal period, a minimum of 1 CPE hour of the required 30 CPE hours shall be in ACPE-accredited provider activities dealing with immunization or vaccine administration. Activities qualifying for the immunization requirement will include the ACPE topic designator of "06" followed by the letter "P" at the end of the universal activity number.

2.12(5) *Reporting CPE credits.*

a. A pharmacist shall provide or report to the board, in the format specified on or with the pharmacist license renewal application, attestation that the CPE requirements have been met.

b. The board may require a pharmacist to submit activity statements of credit or other documented evidence of successful completion of the activities reported as fulfilling the CPE requirements.

2.12(6) *Exemptions and waivers to CPE requirements.*

a. Credit for health-related graduate studies. A pharmacist who is continuing formal education in a health-related graduate program, including participation in a pharmacy residency program, may be granted credit for health-related learning during the period of such enrollment or participation. As an alternative to requesting credit for health-related learning, the pharmacist may complete a CPD portfolio pursuant to rule 657—2.17(272C).

(1) An applicant for credit for health-related learning shall petition the board, as soon as possible following enrollment in the qualifying graduate program or commencement of the pharmacy residency program and prior to completion of the qualifying program, on forms provided by the board.

(2) At the discretion of the board, credit granted for health-related learning during part-time or short-term enrollment in a health-related graduate program may be prorated for the actual period of such enrollment.

b. Exemption for new license holders licensed by examination. After the initial license is issued by examination, the licensee is exempt from meeting CPE 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 657—2.16(235B,272C).

c. Waiver from CPE requirements due to physical disability or illness. The board may, in individual cases involving physical disability or illness, grant a waiver pursuant to 657—Chapter 34 of the minimum CPE requirements or an extension of time within which to fulfill the same or make the required reports. The board may grant a waiver of the minimum CPE 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 CPE requirements by any method prescribed by the board. A waiver request pursuant to this paragraph and 657—Chapter 34 shall be signed by the licensee and the licensee's physician.

d. Active military duty. A licensee shall be deemed compliant with the CPE requirements of this rule during periods that the licensee serves honorably on active duty in the military services.

e. Nonresident. A licensee who is not actively practicing in Iowa, is a resident of another state, and holds an active pharmacist license in the licensee's home state during the renewal period shall be deemed compliant with the CPE requirements of this rule.

[**ARC 8672B**, IAB 4/7/10, effective 5/12/10; **ARC 9406B**, IAB 3/9/11, effective 4/13/11; **ARC 9782B**, IAB 10/5/11, effective 11/9/11; **ARC 0595C**, IAB 2/6/13, effective 3/13/13; **ARC 4579C**, IAB 7/31/19, effective 9/4/19]

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 nonrefundable fee and has met Iowa requirements for CPE or has completed a CPD portfolio pursuant to rule 657—2.17(272C). 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.

2.13(2) *Inactive license.* Failure of a pharmacist to comply with the CPE or CPD requirements during the renewal period shall result in the issuance of a renewal card marked "inactive" upon submission of the renewal application and nonrefundable 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 may be required to obtain a pharmacist-intern registration, including payment of the appropriate nonrefundable registration fee, and 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 2.4(1);

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

(3) Obtain one and one-half times the number of CPE credits required under subrule 2.12(1) for each renewal period the pharmacist was inactive; or

(4) Complete a CPD portfolio pursuant to rule 657—2.17(272C) identifying a minimum of 45 learning outcomes 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 subrule 2.4(1);

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

(3) Obtain one and one-half times the number of CPE credits required under subrule 2.12(1) for each renewal period the pharmacist was inactive; or

(4) Complete a CPD portfolio pursuant to rule 657—2.17(272C) identifying a minimum of 45 learning outcomes 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 subrule 2.4(1);

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

(3) Obtain one and one-half times the number of CPE credits required under subrule 2.12(1) for each renewal period the pharmacist was inactive; or

(4) Complete a CPD portfolio pursuant to rule 657—2.17(272C) identifying a minimum of 45 learning outcomes for each renewal period the pharmacist was inactive.

[**ARC 0595C**, IAB 2/6/13, effective 3/13/13; **ARC 4579C**, IAB 7/31/19, effective 9/4/19]

657—2.14(147,155A) Fees for additional license certificates and verification.

2.14(1) Only original license certificates issued by the board for licensed pharmacists are valid. Additional original license certificates for licensed pharmacists may be obtained from the board for a prepaid nonrefundable fee of $20 each. The fee shall be considered a repayment receipt as defined in Iowa Code section 8.2.

2.14(2) The board may require the submission of a nonrefundable fee of $15 for written license verification.
[**ARC 4579C**, IAB 7/31/19, effective 9/4/19]

657—2.15(155A) Notifications to the board.

2.15(1) *Reporting licensee changes.* A licensee shall report to the board within ten days a change of the licensee's name, address, email address, or pharmacy employment. Except for a change in name, an update to the licensee's personal online profile through the board's online database shall satisfy this subrule.

2.15(2) *Reporting criminal convictions and pleas.* A licensee who has been convicted of, or entered a plea of guilty, nolo contendere, or no contest to, a crime, other than a minor traffic offense, shall report such conviction or plea to the board within 30 days of adjudication.

2.15(3) *Reporting of disciplinary action.* A licensee who has been the subject of disciplinary action in another state, to include but not be limited to citations, reprimands, fines, license restrictions, probation, or license surrender, suspension, or revocation, shall report such action to the board within 30 days of adjudication.
[**ARC 4579C**, IAB 7/31/19, effective 9/4/19]

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 abuse education training provided by the Iowa department of human services 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 six months of initial employment or self-employment. The pharmacist shall complete at least one hour of additional child abuse identification and reporting training every three 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 six months of initial employment or self-employment. The pharmacist shall complete at least one hour of additional dependent adult abuse identification and reporting training every three years.

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 three years following the date of the training. The board may audit this information at any time within the three-year period.
[**ARC 4796C**, IAB 12/4/19, effective 1/8/20]

657—2.17(272C) Continuing professional development portfolio. A pharmacist may complete and submit with the pharmacist's license renewal a CPD portfolio to fulfill the CPE requirements in rule 657—2.12(272C).

2.17(1) *Prerequisite.* A pharmacist, prior to submitting the pharmacist's initial CPD portfolio, shall complete an ACPE-accredited provider activity regarding the objectives and processes relating to CPD. Record of the pharmacist's participation in this prerequisite activity shall be included in the pharmacist's initial CPD portfolio.

2.17(2) *CPD portfolio requirements.* A pharmacist shall combine traditional CPE activities with professional development activities. The pharmacist shall incorporate the record of completion and evaluation of any traditional CPE activities into the CPD portfolio.

a. The pharmacist is responsible for ensuring that the activity content identified in the CPD portfolio directly relates to the pharmacist's professional practice and career goals.

b. The pharmacist is responsible for ensuring that the activities identified in the CPD portfolio comply with the CPE topic requirements identified in subrules 2.12(4) and 2.17(3).

2.17(3) *CPD portfolio content.* In addition to the record of completion of the one-time prerequisite activity identified in subrule 2.17(1), a completed CPD portfolio shall include or identify the following:

a. A minimum of 30 documented learning outcomes in the form of completed learning statements on forms provided by the board.

b. Documented learning outcomes shall include a minimum of two outcomes relating to patient or medication safety, two outcomes relating to pharmacy law, 15 outcomes relating to drug therapy, and if the pharmacist is engaged in the administration of immunizations or vaccines, one outcome relating to vaccine administration.

c. Documented learning outcomes shall include any number of CPE activities that carry the seal of an ACPE-accredited provider. Successful completion and record of these CPE activities in CPE Monitor as provided in subrule 2.12(3), in addition to the documented CPD learning outcomes, is required for the pharmacist to receive credit for these activities.

d. Documented learning outcomes shall include any CPE activities provided by non-ACPE, accredited, health-professional continuing education providers pursuant to paragraph 2.12(2)*"b."*

2.17(4) *CPD portfolio review.* The board shall review or may contract for peer review of CPD portfolios submitted for pharmacist license renewal. The board shall respond to a submitting pharmacist with comments, suggestions, and recommendations regarding the pharmacist's CPD portfolio and processes.

[**ARC 0595C**, IAB 2/6/13, effective 3/13/13; **ARC 4579C**, IAB 7/31/19, effective 9/4/19]

657—2.18(147,155A) Temporary license. Upon submission of the completed applications for licensure by license transfer pursuant to rule 657—2.9(147,155A), all required nonrefundable application fees, the completed fingerprint packet and signed waiver form to facilitate a national criminal history background check pursuant to subrule 2.3(2) and determination that the applicant satisfies all requirements for licensure with the exception of the jurisprudence examination, an applicant for licensure by license transfer may, pursuant to this rule, request a temporary pharmacist license while the applicant completes the MPJE, Iowa Edition, as required in subrule 2.9(3).

2.18(1) *Fee.* The nonrefundable fee for issuance or renewal of a temporary pharmacist license shall be $20.

2.18(2) *Duration.* A temporary pharmacist license issued pursuant to this rule shall be valid for a period of three months. A temporary pharmacist license may be renewed one time for an additional period of three months. In order to qualify for renewal of the temporary license, the pharmacist must request renewal on a form provided by the board and demonstrate at least one attempt to take the MPJE, Iowa Edition, or demonstrate that the examination could not be scheduled within the initial temporary licensure period. A temporary pharmacist license is limited to one renewal.

2.18(3) *Conversion of license.* Upon successful completion of the MPJE, Iowa Edition, the pharmacist license shall cease to be a temporary license and shall be issued as a permanent pharmacist license subject to an expiration date in accordance with rule 657—2.11(147,155A).

[**ARC 5750C**, IAB 7/14/21, effective 8/18/21]

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.

"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.

"Pharmacy support person" 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 responsibility and supervision pursuant to 657—Chapter 5.

"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 rule 657—3.21(155A), and includes a certified pharmacy technician and a pharmacy technician trainee.

"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.

"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 657—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 a licensed pharmacy in Iowa and who is responsible for the actions of a pharmacy technician or other supportive personnel.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

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 certified pharmacy technician or 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.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15]

657—3.3(155A) Registration required. Any person employed in Iowa as a pharmacy technician shall obtain and maintain during such employment a current registration as a certified pharmacy technician or pharmacy technician trainee pursuant to these rules. An individual commencing employment as a pharmacy technician in Iowa who fails to register as a certified pharmacy technician or pharmacy technician trainee as provided by these rules may be subject to disciplinary sanctions. A certified pharmacy technician commencing employment as a certified pharmacy technician in Iowa who fails to register as a certified pharmacy technician or who fails to maintain national certification may be subject to disciplinary sanctions. A pharmacist-intern with a current registration or a pharmacist with a current license is not required to obtain a pharmacy technician registration to work as a pharmacy technician.

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 certified pharmacy technician or pharmacy technician trainee pursuant to these rules.

3.3(2) *Registration required.* Beginning July 1, 2021, any person not currently registered with the board as a pharmacy technician shall obtain registration prior to commencement of employment in an Iowa pharmacy as a pharmacy technician. Through June 30, 2021, any person not currently registered with the board as a pharmacy technician shall submit a completed application for registration within 30 days of accepting employment in an Iowa pharmacy as a pharmacy technician.

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 prior to the commencement of pharmacy technician training.

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

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 9407B**, IAB 3/9/11, effective 4/13/11; **ARC 1785C**, IAB 12/10/14, effective 1/14/15; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

657—3.4 Reserved.

657—3.5(155A) Certification of pharmacy technicians. Except as provided in subrule 3.5(1), all pharmacy technicians shall be required to be nationally certified as provided by this rule. National certification acquired through successful completion of any NCCA-accredited pharmacy technician certification program and examination fulfills the requirement for national certification. National certification does not replace 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. A certified pharmacy technician shall maintain the technician's national certification, in addition to the technician's Iowa registration, during any period of employment in an Iowa pharmacy as a certified pharmacy technician.

3.5(1) *Pharmacy technician trainee.* 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(2) *Certified pharmacy technician.* All applicants for a new pharmacy technician registration except as provided by subrule 3.5(1), 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.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 9407B**, IAB 3/9/11, effective 4/13/11; **ARC 1785C**, IAB 12/10/14, effective 1/14/15]

657—3.6(155A) Extension of deadline for national certification. Rescinded **ARC 1785C**, IAB 12/10/14, effective 1/14/15.

657—3.7 Reserved.

657—3.8(155A) Application.

3.8(1) An applicant shall submit a completed application along with the appropriate nonrefundable application fee pursuant to rule 657—3.9(155A) or 657—3.10(155A).

3.8(2) The application shall include:

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

b. Current place or places of employment;

c. Criminal or disciplinary action history;

d. If the application is for certified pharmacy technician registration, documentation of current national pharmacy technician certification; and

e. Any other information deemed necessary by the board.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

657—3.9(155A) Registration fee and term—technician trainee.

3.9(1) *Fee.* The nonrefundable application fee for a pharmacy technician trainee registration shall be $20. The nonrefundable application fee for a pharmacy technician trainee registration shall be submitted in the form of a personal check, certified check, cashier's check, or money order made payable to the Iowa Board of Pharmacy when submitted with a written application or by acceptable debit or credit card when submitted with an online application.

3.9(2) *Term.* A pharmacy technician trainee registration shall expire on the last day of the registration month 12 months following the date of registration. A pharmacy technician trainee registration shall not be renewed.

a. *National certification completed.* When the registered pharmacy technician trainee completes national certification, and no later than the expiration of the pharmacy technician trainee registration, the technician shall submit a completed application and nonrefundable application fee for certified pharmacy technician registration.

b. *Expiration of registration.* The registration of a pharmacy technician trainee who fails to complete national certification prior to the expiration of the registration shall expire and the technician shall cease practice as a pharmacy technician.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

657—3.10(155A) Registration fee, term, and renewal—certified pharmacy technician.

3.10(1) *Fee.* The nonrefundable application fee for a certified pharmacy technician registration shall be $40 per biennium. The nonrefundable application fee for a certified pharmacy technician registration shall be submitted in the form of a personal check, certified check, cashier's check, or money order made payable to the Iowa Board of Pharmacy when submitted with a written application or by acceptable debit or credit card when submitted with an online application.

3.10(2) *Term.* A certified pharmacy technician registration shall expire on the date that the technician's national certification expires.

3.10(3) *Renewal.* A certified pharmacy technician registration shall be renewed prior to the expiration of the registration.

a. *Delinquent registration grace period.* A certified pharmacy technician registration which is not renewed prior to the expiration of the registration shall be considered delinquent. Renewal during the month following the expiration date of the registration shall include the nonrefundable registration fee pursuant to subrule 3.10(1) and a nonrefundable late penalty fee of $40. A registered certified pharmacy technician who renews during the month following the expiration date of the registration shall not be subject to disciplinary action for continuing to practice as a pharmacy technician during the delinquency of the registration.

b. *Registration reactivation beyond grace period.* If the registration is not renewed prior to the expiration of the one-month grace period identified in paragraph 3.10(3)*"a,"* the technician shall cease the practice as a pharmacy technician until the registration is reactivated. A certified pharmacy technician without a current registration may apply for registration reactivation by submitting a completed application for reactivation and a nonrefundable reactivation fee of $160. 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.

c. *Voluntary cancellation.* A registered certified pharmacy technician who ceases practice as a pharmacy technician and does not intend to renew the registration prior to its expiration may request that the board cancel the registration. If the certified pharmacy technician later seeks registration as a

certified pharmacy technician, the technician shall not be assessed a late penalty fee or reactivation fee for renewal of the registration.
[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 1785C**, IAB 12/10/14, effective 1/14/15; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

657—3.11(155A) Verification fee. The board may require the submission of a nonrefundable fee of $15 for written verification of a registration.
[**ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

657—3.12(155A) Registration certificates. Rescinded **ARC 5542C**, IAB 4/7/21, effective 5/12/21.

657—3.13(155A) Notifications to the board. A pharmacy technician shall report to the board within ten days a change of the technician's name, address, or pharmacy employment status.
[**ARC 9009B**, IAB 8/11/10, effective 7/23/10]

657—3.14 to **3.16** Reserved.

657—3.17(155A) Training and utilization of pharmacy technicians.

3.17(1) *Policies and procedures.* All licensed pharmacies located in Iowa that utilize 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.

3.17(2) *Documented training.* Pharmacy technician training shall be documented and maintained by the pharmacy for the duration of employment.

3.17(3) *Vaccine administration training and continuing education.* A pharmacy technician who administers a vaccine or immunization under the supervision of a pharmacist shall document successful completion of the requirements in paragraph 3.17(3)*"a"* or *"b"* and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 3.17(3)*"c."*

a. Initial qualification. Except as provided in paragraph 3.17(3)*"b,"* a technician shall have successfully completed an Accreditation Council for Pharmacy Education (ACPE)-accredited program on vaccine administration that is an evidence-based program 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 (CDC) 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) Immunization record management; and
(9) Identification of adverse events.

b. Previous qualification. A technician who is currently licensed as a registered nurse shall be deemed to have met the training requirement.

c. Continuing education. During any technician registration renewal period, a technician who engages in the administration of vaccines shall complete and document at least one hour of ACPE-approved continuing education with the ACPE topic designator "06" followed by the letter "T" or "P."

d. Certification maintained. During any period within which a technician may engage in the administration of vaccines, the technician shall maintain current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.
[**ARC 1785C**, IAB 12/10/14, effective 1/14/15; **ARC 5820C**, IAB 8/11/21, effective 7/15/21]

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.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10]

657—3.19 Reserved.

657—3.20(155A) Responsibility of supervising pharmacist. The ultimate responsibility for the actions of a pharmacy technician shall remain with the supervising pharmacist. A pharmacy license holder shall not infringe on the authority of a supervising pharmacist to delegate or decline to delegate specific functions to a pharmacy technician based on the supervising pharmacist's professional judgment regarding the knowledge and training of the technician.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

657—3.21(155A) Delegation of functions.

Pursuant to established policies and procedures and the supervising pharmacist's professional judgment, a supervising pharmacist may delegate any technical or nontechnical functions in the operation of the pharmacy, except those which are prohibited pursuant to rule 657—3.23(155A), to an appropriately trained and registered pharmacy technician, but only if the pharmacist is on site and available to supervise the pharmacy technician when delegated functions are performed, except as provided in rule 657—6.7(124,155A) or 657—7.6(155A), as appropriate, or as provided for telepharmacy in 657—Chapter 13. Except as provided for an approved technician product verification program pursuant to 657—Chapter 40, 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. A pharmacy technician shall not delegate technical functions to a pharmacy support person.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9783B**, IAB 10/5/11, effective 11/9/11; **ARC 4189C**, IAB 12/19/18, effective 1/23/19; **ARC 5007C**, IAB 3/25/20, effective 4/29/20; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

657—3.22(155A) Technical functions. Rescinded **ARC 5542C**, IAB 4/7/21, effective 5/12/21.

657—3.23(155A) Functions a pharmacy technician shall not perform.

3.23(1) *Prohibited functions for all pharmacy technicians.* A pharmacy technician shall not be authorized to perform any of the following functions:

a. Except for a certified pharmacy technician participating in an approved technician product verification program pursuant to 657—Chapter 40, provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;

b. Conduct prospective drug use review or evaluate a patient's medication record for purposes identified in rule 657—8.21(155A);

c. 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;

d. Make decisions that require a pharmacist's professional judgment, such as interpreting prescription drug orders or applying information;

e. Transfer a prescription drug order for a controlled substance to another pharmacy or receive the transfer of a prescription drug order for a controlled substance from another pharmacy;

f. Delegate technical functions to a pharmacy support person.

3.23(2) *Prohibited functions for technician trainees.* In addition to the prohibited functions in subrule 3.23(1), a technician trainee shall not be authorized to perform any of the following functions:

a. Accept new prescription drug orders or medication orders communicated to the pharmacy by a prescriber or the prescriber's agent.

b. Transfer or receive by transfer by any means the original prescription drug order information or prescription refill information of a prescription for any substance.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 9783B**, IAB 10/5/11, effective 11/9/11; **ARC 4189C**, IAB 12/19/18, effective 1/23/19; **ARC 5007C**, IAB 3/25/20, effective 4/29/20; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

657—3.24(155A) New prescription drug orders or medication orders. Rescinded **ARC 5542C**, IAB 4/7/21, effective 5/12/21.

657—3.25(155A) Delegation of nontechnical functions. Rescinded IAB 4/7/10, effective 6/1/10.

657—3.26 and **3.27** Reserved.

657—3.28(147,155A) Unethical conduct or practice. Violation by a pharmacy technician 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 657—3.31(155A).

3.28(1) *Misrepresentative deeds.* A pharmacy technician 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 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 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.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

657—3.29(155A) Denial of registration. The executive director or designee may deny an application for registration as a 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, 124B, 126, 147, 155A, or 205 or any rule of the board.

An individual whose application for registration as a 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.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

657—3.30(155A) Reporting discipline and criminal convictions. A registered pharmacy technician shall provide to the board written notice of and unredacted documents related to any disciplinary or enforcement action imposed by any licensing agency or regulatory authority on any license or registration held by the registered pharmacy technician no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. A registered pharmacy technician shall provide written notice to the board of any criminal conviction that is related to the practice of pharmacy or controlled substances no later than 30 days after the conviction. The term "criminal conviction" includes instances when the judgment of conviction or sentence is deferred.
[**ARC 5542C**, IAB 4/7/21, effective 5/12/21]

657—3.31(155A) Discipline of pharmacy technicians.

3.31(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, 124B, 126, 147, 155A, or 205 or any rule of the board.

3.31(2) *Sanctions.* The board may impose the following disciplinary sanctions:

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

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

c. Nonrenewal of a 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.

[**ARC 9009B**, IAB 8/11/10, effective 7/23/10; **ARC 1785C**, IAB 12/10/14, effective 1/14/15; **ARC 3857C**, IAB 6/20/18, effective 7/25/18; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

These rules are intended to implement Iowa Code sections 147.72, 147.80, 147.107, 155A.6A, 155A.23, 155A.33, 155A.34, and 155A.39.

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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.

"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 657—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 657—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.

[**ARC 9784B**, IAB 10/5/11, effective 11/9/11; **ARC 1406C**, IAB 4/2/14, effective 5/7/14]

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 commencement of the first professional year in a college of pharmacy. Internship shall consist of a minimum of 1500 hours, all 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. A pharmacist-intern may acquire additional

hours 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 657—4.2(155A) apply. Credit toward any additional hours will be allowed, at a rate not to exceed 10 hours per week, for an internship served concurrent with academic training and outside a college-based clinical program. "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 winter break, shall not be considered "concurrent time." The competencies in subrule 4.2(2) and the concurrent time limitations of this rule shall not apply to college-based clinical programs.
[**ARC 1406C**, IAB 4/2/14, effective 5/7/14]

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 657—4.3(155A). Registration is required of all students enrolled in Iowa colleges of pharmacy upon commencement of the first professional year in the college of pharmacy. Colleges of pharmacy located in Iowa shall annually certify to the board the names of students who are enrolled in the first professional year in the college of pharmacy. Colleges of pharmacy located in Iowa shall, within two weeks of any change, certify to the board the names of students who have withdrawn from the college of pharmacy.

4.6(1) *Application for registration—required information.* Application for registration as a pharmacist-intern shall be on forms provided by the board, and all requested information shall be provided on or with such application. The application shall require that the applicant provide, at a minimum, the following: name; address; telephone number; date of birth; social security number or individual tax identification number (ITIN); and name and location of college of pharmacy and anticipated month and year of graduation. The college of pharmacy shall certify the applicant's eligibility to practice as a pharmacist-intern. If the applicant provides an ITIN in lieu of a social security number, the applicant shall also provide acceptable proof of lawful presence in the United States.

4.6(2) *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. At the discretion of the supervising pharmacist, clinical and judgmental functions may be delegated to a registered pharmacist-intern depending upon which functions are appropriate to the pharmacist-intern's level of education and training.

4.6(3) *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 657—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 in the pursuit of a degree in pharmacy; or

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

4.6(4) *Identification.*

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 a name badge that is visible to the public and includes the designation "pharmacist-intern," "pharmacy student," or "student-pharmacist."

4.6(5) *Internship credit.*

a. 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 will not be granted unless registration is issued before the student begins the program. Credit for internship experience will not be granted unless registration and other required records or affidavits are completed.

b. Notarized affidavits of experience in non-college-sponsored programs shall be submitted to the board no later than six months following graduation from a school or college of pharmacy. These affidavits shall certify only the number of hours and dates of training obtained outside a college-based clinical program as provided in rule 657—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.

4.6(6) *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 657—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 657—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 657—4.3(155A) or 657—4.7(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.

[**ARC 9784B**, IAB 10/5/11, effective 11/9/11; **ARC 1406C**, IAB 4/2/14, effective 5/7/14; **ARC 1786C**, IAB 12/10/14, effective 1/14/15; **ARC 2405C**, IAB 2/17/16, effective 3/23/16; **ARC 3858C**, IAB 6/20/18, effective 7/25/18; **ARC 4579C**, IAB 7/31/19, effective 9/4/19; **ARC 5544C**, IAB 4/7/21, effective 5/12/21]

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 pharmacy licensed in a state or territory of the United States or other board-approved location that provides experience in community, institutional, and clinical pharmacy practices.

4.7(1) *Registration.* Candidates shall register with the board as provided in rule 657—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).

4.7(2) *Certification of hours.* Following completion of any period of internship, internship hours shall be certified to the board by submission of notarized affidavits of experience as provided in paragraph 4.6(4)*"c."*

[**ARC 1406C**, IAB 4/2/14, effective 5/7/14; **ARC 4579C**, IAB 7/31/19, effective 9/4/19; **ARC 5544C**, IAB 4/7/21, effective 5/12/21]

657—4.8(155A) Fees. The fee for registration as a pharmacist-intern is $30, which shall be payable with the application. The board may require the submission of a nonrefundable fee of $15 for written registration verification or certification of internship hours.
[**ARC 5544C**, IAB 4/7/21, effective 5/12/21]

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 657—4.1(155A).

4.9(2) *Affidavits.* A preceptor shall be responsible for completing the affidavit certifying the number of hours and the dates of each internship training period under the supervision of the preceptor for any period of internship completed outside a college-based clinical program.

4.9(3) *Number of interns.* For the purpose of internship, 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.
[**ARC 1406C**, IAB 4/2/14, effective 5/7/14; **ARC 4266C**, IAB 1/30/19, effective 3/6/19]

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, 124B, 126, 147, 155A or 205, or any rule of the board.
[**ARC 3857C**, IAB 6/20/18, effective 7/25/18]

657—4.11(155A) Notifications to the board.

4.11(1) *Reporting registration changes.* A registered pharmacist-intern shall report to the board within ten days a change of the pharmacist-intern's name, address or email address. Except for a change in name, an update to the pharmacist-intern's personal online profile through the board's online database shall satisfy this subrule.

4.11(2) *Reporting criminal convictions and pleas.* A registered pharmacist-intern who has been convicted of a crime, or entered a plea of guilty, nolo contendere, or no contest to a crime, other than a minor traffic offense, shall report such conviction or plea to the board within 30 days of adjudication.

4.11(3) *Reporting disciplinary action.* A registered pharmacist-intern who has been the subject of disciplinary action in another state, including but not limited to citations, reprimands, fines, license restrictions, probation, license or registration surrender, suspension, or revocation, shall report such action to the board within 30 days of adjudication.
[**ARC 5544C**, IAB 4/7/21, effective 5/12/21]

657—4.12(155A) Discipline of pharmacist-interns.

4.12(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, 124B, 126, 147, 155A, or 205, or any rule of the board.

4.12(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.
[**ARC 3857C**, IAB 6/20/18, effective 7/25/18; **ARC 5544C**, IAB 4/7/21, effective 5/12/21]

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

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CHAPTER 5
PHARMACY SUPPORT PERSONS

657—5.1(155A) Definitions. For purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

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

"Direct access" means physical access, without direct supervision by a pharmacist, to opened, unpackaged, or unsecured stock containers or prescription vials containing prescription drugs.

"Pharmacy clerk" means a person whose duties within the pharmacy department include accessing filled prescription orders and processing payments for and delivering such orders to the patient or the patient's agent under the supervision of a pharmacist.

"Pharmacy support person" means a person, other than a licensed pharmacist, a registered pharmacist-intern, or a registered pharmacy technician, who may perform nontechnical duties assigned by a supervising pharmacist under the pharmacist's responsibility and supervision.

"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, and who is registered pursuant to 657—Chapter 3, and includes a certified pharmacy technician, a pharmacy technician trainee, and an uncertified pharmacy technician.

"Secure package" means the prescription order is enclosed in tamper-evident packaging. An IV bag is considered tamper-evident packaging.

"Supervising pharmacist" means an Iowa-licensed pharmacist who is on duty in an Iowa-licensed pharmacy and who is responsible for assigning and supervising the duties performed by a pharmacy support person.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9009B**, IAB 8/11/10, effective 7/23/10]

657—5.2(155A) Purpose of registration. A registration program for pharmacy support persons is established for the purposes of identification, tracking, and disciplinary action. The registration shall not include any determination of the competency of the registered individual. The use of pharmacy support persons to assist the pharmacist with nontechnical duties associated with the practice of pharmacy enables the pharmacist to provide pharmaceutical care to the patient.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.3 Reserved.

657—5.4(155A) Registration required. Unless exempt in rule 657—5.5(155A), any individual employed by a pharmacy who has direct access to prescription drugs or confidential patient information must be registered as a pharmacy support person. Beginning July 1, 2021, prior to commencing employment in an Iowa pharmacy as a pharmacy support person, an individual shall obtain registration as a pharmacy support person. Any registered pharmacy support person who discontinues employment as a pharmacy support person shall not be required to maintain a registration and shall request cancellation of the registration as provided in subrule 5.9(3).

Through June 30, 2021, any person required to register and not previously registered with the board as a pharmacy support person shall complete an application for registration within 30 days of accepting employment in an Iowa pharmacy as a pharmacy support person. Such application shall be received in the board office before the expiration of this 30-day period.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 5543C**, IAB 4/7/21, effective 5/12/21; Editorial change: IAC Supplement 9/8/21]

657—5.5(155A) Exempt from registration. The following shall be exempt from registration as a pharmacy support person:

1. A licensed pharmacist, registered pharmacist-intern, or registered pharmacy technician.

2. Facility maintenance personnel including but not necessarily limited to cleaning, sanitation, structural, and mechanical maintenance personnel. Facility maintenance personnel deemed exempt

from registration shall be directly supervised by a pharmacist or a certified pharmacy technician who is responsible for the maintenance person's activities within the pharmacy department to ensure medication security and patient privacy.

3. Any person not directly employed by or under contract to the pharmacy, and not under the direct supervision of a pharmacist, who provides data processing, data processing support, programming, maintenance, billing, delivery, or administrative support functions outside the pharmacy department.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 5543C**, IAB 4/7/21, effective 5/12/21]

657—5.6 Reserved.

657—5.7(155A) Registration application form.

5.7(1) *Required information.* The application form for a pharmacy support person registration shall require 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. Work experience;

c. Current place or places of employment;

d. Any other information deemed necessary by the board.

5.7(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 support person with reasonable skill and safety.

5.7(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).

5.7(4) *History of disciplinary actions.* The applicant shall declare any history of disciplinary actions or practice restrictions imposed by a state health care professional, licensure, or registration authority.

5.7(5) *Sworn signature.* The applicant shall sign the application under penalty of perjury and shall submit the application to the board with the appropriate nonrefundable fees pursuant to rule 657—5.9(155A).

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 5543C**, IAB 4/7/21, effective 5/12/21]

657—5.8 Reserved.

657—5.9(155A) Registration fee, term, and renewal.

5.9(1) *Fee.* The nonrefundable application fee for a pharmacy support person registration shall be $25. The nonrefundable application fee for a pharmacy support person registration shall be submitted in the form of a personal check, certified check, cashier's check, or money order made payable to the Iowa Board of Pharmacy when submitted with a written application or by acceptable debit or credit card when submitted with an online application.

5.9(2) *Term.* A pharmacy support person registration shall expire on the second last day of the birth month following initial registration. Registration shall not require continuing education for renewal.

5.9(3) *Renewal.* A pharmacy support person registration shall be renewed prior to the expiration of the registration.

a. Delinquent registration grace period. A pharmacy support person registration which is not renewed prior to the expiration of the registration shall be considered delinquent. Renewal during the month following the expiration date of the registration shall include the nonrefundable registration fee pursuant to subrule 5.9(1) and a nonrefundable late penalty fee of $25. A registered pharmacy support person who renews during the month following the expiration date of the registration shall not be subject to disciplinary action for continuing to practice as a pharmacy support person during the delinquency of the registration.

b. Registration reactivation beyond grace period. If the registration is not renewed prior to the expiration of the one-month grace period identified in paragraph 5.9(3)*"a,"* the individual shall cease practice as a pharmacy support person until the registration is reactivated. A pharmacy support person

with an expired registration may apply for registration reactivation by submitting a completed application for reactivation and a nonrefundable reactivation fee of $100. An individual who continues employment as a pharmacy support person with an expired registration, in addition to the pharmacy and the pharmacist in charge that allow the individual to continue practice as a pharmacy support person, may be subject to disciplinary sanctions.

c. Voluntary cancellation. A registered pharmacy support person who ceases practice as a pharmacy support person and does not intend to renew the registration prior to its expiration may request that the board cancel the registration. If the pharmacy support person later seeks registration as a pharmacy support person, the individual shall not be assessed a late penalty fee or reactivation fee for renewal of the registration.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 5543C**, IAB 4/7/21, effective 5/12/21]

657—5.10(155A) Registration renewal. Rescinded **ARC 5543C**, IAB 4/7/21, effective 5/12/21.

657—5.11(155A) Late application. Rescinded **ARC 5543C**, IAB 4/7/21, effective 5/12/21.

657—5.12 Reserved.

657—5.13(155A) Registration verification. The board may require the submission of a nonrefundable fee of $15 for written verification of a registration.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 5543C**, IAB 4/7/21, effective 5/12/21]

657—5.14(155A) Notifications to the board. A registered pharmacy support person shall report to the board within ten days a change of name, address, place of employment, or employment status.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 5543C**, IAB 4/7/21, effective 5/12/21]

657—5.15(155A) Identification of pharmacy support person.

5.15(1) *Name badge.* A pharmacy support person shall wear a name badge or other form of identification while on duty which clearly identifies the person as a pharmacy support person.

5.15(2) *Misrepresentation prohibited.* A pharmacy support person shall not, in any manner, represent himself or herself as a pharmacist, a pharmacist-intern, or a pharmacy technician.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.16 Reserved.

657—5.17(155A) Tasks a pharmacy support person shall not perform. A pharmacy support person shall not perform any of the following judgmental or technical functions. Performance of any of these tasks by a pharmacy support person shall constitute the practice of pharmacy without a license in violation of Iowa Code section 155A.7. A pharmacy support person 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; make an offer of patient counseling on behalf of the 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 or applying information.
5. Accept by oral communication any new or refill prescription authorizations communicated to a pharmacy by a prescriber or by the prescriber's office or contact a prescriber to obtain prescription refill authorizations.
6. Provide a prescription or drug to a patient without a pharmacist's verification as to the accuracy of the dispensed medication and without the physical presence of a pharmacist.

7. Package, pour, or place in a container for dispensing, sale, distribution, transfer, vending, or barter any drug which, under federal or state laws, may be sold or dispensed only pursuant to the prescription of a practitioner authorized to prescribe drugs. This prohibited task includes the addition of water or other liquid for reconstitution of oral antibiotic liquids. A pharmacy support person may place a prescription container into a bag or sack for delivery to the patient as part of the sales transaction after the accuracy of the prescription has been verified by the pharmacist.

8. Affix required prescription labels upon any container of drugs sold or dispensed pursuant to the prescription of an authorized prescriber.

9. Process or enter, including entry into the pharmacy computer system, pertinent clinical patient or prescription information, including allergies and disease state information.

10. Prepackage or label multidose and single-dose packages of drugs, including dose picks for unit dose cart fills for hospital or long-term care facility patients.

11. Check or inspect drug supplies provided and controlled by an Iowa-licensed pharmacy but located or maintained outside the pharmacy department, 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.

12. Reconstitute prefabricated noninjectable medication, prepare parenteral products, or compound sterile or nonsterile drug products.

13. Communicate, transmit, or receive patient or prescription information to or from the pharmacy for the purpose of transferring a patient's prescription between pharmacies.

14. Assist with or witness the destruction or wastage of controlled substances pursuant to 657—subrule 10.22(2).

15. Perform any technical functions pursuant to 657—Chapter 3 that may be delegated to a pharmacy technician.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9785B**, IAB 10/5/11, effective 11/9/11; **ARC 3637C**, IAB 2/14/18, effective 3/21/18; **ARC 5543C**, IAB 4/7/21, effective 5/12/21]

657—5.18(155A) Nontechnical pharmacy support tasks. Rescinded **ARC 5543C**, IAB 4/7/21, effective 5/12/21.

657—5.19 Reserved.

657—5.20(155A) Training and utilization of pharmacy support persons. All Iowa-licensed pharmacies utilizing pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy support persons. Pharmacy policies shall specify the frequency of review. Pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Such policies and procedures and documentation of pharmacy support person training shall be available for inspection by the board or an agent of the board.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—5.21(155A) Delegation of functions and responsibility of supervising pharmacist. Pursuant to established policies and procedures and the supervising pharmacist's professional judgment, a supervising pharmacist may delegate nontechnical functions in the operation of the pharmacy, except those which are prohibited pursuant to rule 657—5.17(155A), to an appropriately trained and registered pharmacy support person, but only if the pharmacist is on site and available to supervise the pharmacy support person when delegated functions are performed, except as provided in rule 657—6.7(124,155A) or 657—7.6(155A), as appropriate. The ultimate responsibility for the actions of a pharmacy support person shall remain with the supervising pharmacist. A pharmacy license holder shall not infringe on the authority of a supervising pharmacist to delegate or decline to delegate specific nontechnical functions to a pharmacy support person based on the supervising pharmacist's professional judgment regarding the knowledge and training of the pharmacy support person.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 5543C**, IAB 4/7/21, effective 5/12/21]

657—5.22(155A) Delegation of nontechnical functions. A pharmacist may delegate nontechnical functions to an appropriately trained and registered pharmacy support person, but only if the pharmacist is present to supervise the pharmacy support person when delegated functions are performed, except as provided in rule 657—6.7(124,155A) or 657—7.6(155A), as appropriate.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 4267C**, IAB 1/30/19, effective 3/6/19]

657—5.23 Reserved.

657—5.24(155A) Denial of registration. The board may deny an application for registration as a pharmacy support person 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, 124B, 126, 147, 155A, or 205 or any rule of the board.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

657—5.25(147,155A) Unethical conduct or practice. Violation by a pharmacy support person 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 657—5.27(155A).

5.25(1) *Misrepresentative deeds.* A pharmacy support person 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.

5.25(2) *Confidentiality.* In the absence of express consent from the patient or order or direction of a court, except where the best interests of the patient require, a pharmacy support person 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, or a person duly authorized by law to receive such information the contents of any prescription or the therapeutic effect thereof or the nature of professional pharmaceutical services rendered to a patient; the nature, extent, or degree of illness suffered by any patient; or any medical information furnished by the prescriber.

5.25(3) *Discrimination.* It is unethical for a pharmacy support person to unlawfully discriminate between patients or groups of patients for reasons of religion, race, creed, color, sex, sexual orientation, gender identity, age, national origin, or disease state when providing pharmaceutical services.

5.25(4) *Unethical conduct or behavior.* A pharmacy support person shall not exhibit unethical behavior in connection with the pharmacy support person's pharmacy employment. Unethical behavior shall include, but is not limited to, the following acts: verbal abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, indecent or obscene conduct, and theft.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 5543C**, IAB 4/7/21, effective 5/12/21]

657—5.26(155A) Reporting discipline and criminal convictions. A registered pharmacy support person shall provide to the board written notice of and unredacted documents related to any disciplinary or enforcement action imposed by any licensing agency or regulatory authority on any license or registration held by the registered pharmacy support person no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. A registered pharmacy support person shall provide written notice and unredacted documents to the board of any criminal conviction that is related to the practice of pharmacy or controlled substances no later than 30 days after the conviction. The term "criminal conviction" includes instances when the judgment of conviction or sentence is deferred.
[**ARC 5543C**, IAB 4/7/21, effective 5/12/21]

657—5.27(155A) Discipline of pharmacy support persons.

5.27(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, 124B, 126, 147, 155A, or 205 or any rule of the board.

5.27(2) *Sanctions.* The board may impose the following disciplinary sanctions:

a. Revocation of a pharmacy support person registration.

b. Suspension of a pharmacy support person registration until further order of the board or for a specified period.

c. Nonrenewal of a pharmacy support person 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. Imposition of civil penalties not to exceed $25,000.

g. Issuance of citation and warning.

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

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 3857C**, IAB 6/20/18, effective 7/25/18; **ARC 5543C**, IAB 4/7/21, effective 5/12/21]

These rules are intended to implement Iowa Code sections 147.55, 147.80, 155A.3, 155A.6B, 155A.18 and 155A.23.

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[Editorial change: IAC Supplement 9/8/21]

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 responsibilities identified in rule 657—8.3(155A).

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 0501C**, IAB 12/12/12, effective 1/16/13; **ARC 1961C**, IAB 4/15/15, effective 5/20/15]

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

1. A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.
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.

[**ARC 2196C**, IAB 10/14/15, effective 11/18/15]

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 657—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 and of the provisions for effective control against theft of, diversion of, or unauthorized access to prescription drugs, including those collected through an authorized collection program, records for such drugs and authorized collection program activities, and patient records as provided in 657—Chapters 10 and 21 and federal regulations for authorized controlled substance collection programs, which can be found at www.deadiversion.usdoj.gov/drug_disposal/.

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 subrules 6.7(2) and 6.7(4).

6.7(2) *Temporary absence of pharmacist.* In the temporary absence of the pharmacist, only the pharmacist in charge may designate pharmacy technicians or pharmacy support persons who may be present in the prescription department to perform technical or nontechnical functions, respectively, 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.

a. In the absence of the pharmacist, the pharmacy shall be secured from public access and the pharmacy shall notify the public that the pharmacist is temporarily absent and that no prescriptions will be dispensed until the pharmacist returns. If the pharmacist in charge has authorized the presence in the pharmacy of a pharmacy technician or a pharmacy support person to perform designated functions when the pharmacy is closed, the pharmacy technician or the pharmacy support person may not dispense or deliver any drug, chemical, device, or prepared prescription to a patient or patient's agent.

b. A pharmacy technician or a pharmacy support person 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 pharmacy technician or pharmacy support person 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 or pharmacy support person who prepared the record. The log shall be periodically reviewed by the pharmacist in charge, and documentation of such review shall be maintained for two years from the date of entry.

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.

6.7(4) *Refill sales during pharmacist break.* At the discretion of the on-duty supervising pharmacist and pursuant to established policies and procedures, the pharmacist may delegate to a technician the dispensing of previously verified prescriptions which have been identified to not require pharmacist counseling pursuant to rule 657—6.14(155A) when the pharmacist is on a break of limited duration and is absent from the pharmacy department.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 1308C**, IAB 2/5/14, effective 3/12/14; **ARC 2408C**, IAB 2/17/16, effective 3/23/16; **ARC 3638C**, IAB 2/14/18, effective 3/21/18; **ARC 4189C**, IAB 12/19/18, effective 1/23/19]

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, except as provided in 657—subrule 21.5(1). The original prescription shall be retained by the pharmacy filling the prescription and shall be maintained in the original format as received by the pharmacy. Dispensing documentation shall include the date of fill or refill; the name, strength, and National Drug Code (NDC) of the actual drug product dispensed; and the initials or other unique identification of the pharmacist, pharmacist-intern, or technician in an approved technician product verification program. Dispensing documentation shall be maintained and be readily available.

[**ARC 3638C**, IAB 2/14/18, effective 3/21/18; **ARC 5007C**, IAB 3/25/20, effective 4/29/20]

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(8).

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) *Authorized individuals and means of transmission.* Individuals authorized to engage in the transfer of prescriptions include a pharmacist, a pharmacist-intern under the direct supervision of a pharmacist, and a certified pharmacy technician, except as prohibited in 657—subrule 3.23(1). The transferring individual may transmit the prescription and transfer information required under subrule 6.9(5) from the transferring pharmacy via electronic means pursuant to subrule 6.9(8) or, following direct communication between authorized individuals, via oral or facsimile transmission. The receiving individual shall ensure the prescription transfer record maintained in the receiving pharmacy contains all of the information required under subrule 6.9(7).

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 activity.

6.9(5) *Record of transfer out.* The individual 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 individual receiving the prescription drug order information;

(3) The name of the individual 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) *Record of transfer received.* The individual 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 individual receiving the prescription drug order information;

(7) Name of the individual 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(8) 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(8) *Electronic transfer between pharmacies.* Pharmacies may electronically transfer prescription information, including controlled substance prescription information in compliance with federal regulations for controlled substances. For transfers of prescriptions for noncontrolled substances and controlled substances, pharmacies that share a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization. A prescription for a controlled substance transferred between two pharmacies which do not share a real-time, online database may only be transferred one time.

[**ARC 7634B**, IAB 3/11/09, effective 4/15/09; **ARC 8169B**, IAB 9/23/09, effective 10/28/09; **ARC 0343C**, IAB 10/3/12, effective 11/7/12; **ARC 3638C**, IAB 2/14/18, effective 3/21/18; **ARC 4189C**, IAB 12/19/18, effective 1/23/19; **ARC 5542C**, IAB 4/7/21, effective 5/12/21]

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, except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors, 657—subrule 8.19(8) for opioid antagonists, or 657—subrule 8.19(9) for expedited partner therapy.

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)";

(3) If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the prescription container label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological product)";

h. The initials or other unique identification of the dispensing pharmacist, unless the identification of the pharmacist involved in each step of the prescription filling process is electronically documented and retrievable.

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

[**ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 2414C**, IAB 2/17/16, effective 3/23/16; **ARC 3638C**, IAB 2/14/18, effective 3/21/18; **ARC 4903C**, IAB 2/12/20, effective 3/18/20]

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 contain, at a minimum, the following information:

a. Full name of the patient;

b. Address and telephone number of the patient;

c. Patient's date of birth;

d. Patient's gender;

e. Known allergies;

f. 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 dispensed, and the name of the prescriber; and

g. Pharmacist comments relevant to the patient's health care, 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, supplements, 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).

6.13(4) *Expedited partner therapy.* When a pharmacy dispenses a prescription drug pursuant to Iowa Code section 139A.41 and 657—subrule 8.19(9) for expedited partner therapy, a pharmacy is only required to maintain the information about the patient who is known to the pharmacy.

[**ARC 3638C**, IAB 2/14/18, effective 3/21/18; **ARC 4903C**, IAB 2/12/20, effective 3/18/20]

657—6.14(155A) Patient counseling and instruction. Every pharmacy that is open to the public and located in Iowa shall post in every prescription pickup area, including in every drive-through prescription pickup lane, in a manner clearly visible to patients, a notice that Iowa law requires the pharmacist to discuss with the patient any prescriptions dispensed to the patient that are new or a change in drug therapy.

6.14(1) *Counseling required.* Upon receipt of a new prescription drug order, or upon receipt of a change in drug therapy including but not limited to a change of dose, directions, or drug formulation, and following a prospective drug use review pursuant to rule 657—8.21(155A), a pharmacist or pharmacist-intern 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 select and use alternative forms of patient information which shall include information for the patient or patient's caregiver to contact the pharmacist for further consultation. The manner in which the patient or caregiver contacts the pharmacist shall not cause the patient to incur any expense. "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. 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 counseling was provided.

[**ARC 8540B**, IAB 2/24/10, effective 4/1/10; **ARC 9910B**, IAB 12/14/11, effective 1/18/12; **ARC 3638C**, IAB 2/14/18, effective 3/21/18]

657—6.15(124,126) Return of drugs and devices. For the protection of the public health and safety, prescription drugs and devices 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 or device 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).

[**ARC 3638C**, IAB 2/14/18, effective 3/21/18]

657—6.16(124,155A) Records. Every 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 record or last activity except as specifically identified by law or rule. Controlled substances 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) *Storage of records.* Original hard-copy prescriptions and other pharmacy records shall be maintained by the pharmacy for a minimum of two years from the date of the record in accordance with this subrule.

a. Records shall be maintained within the licensed pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the licensed pharmacy department, including at a remote location, if the pharmacy has retained an electronic copy of the records in the pharmacy that is immediately available and if the original records are available within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

b. Records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department, including at a remote location, if the records are retrievable within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

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, except as provided in 657—subrule 21.5(1).

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 record.

[**ARC 7636B**, IAB 3/11/09, effective 4/15/09; **ARC 8539B**, IAB 2/24/10, effective 4/1/10; **ARC 3638C**, IAB 2/14/18, effective 3/21/18; **ARC 5007C**, IAB 3/25/20, effective 4/29/20]

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 illnesses to which patients 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.
[**ARC 9911B**, IAB 12/14/11, effective 1/18/12]

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 responsibilities identified in rule 657—8.3(155A). Where 24-hour operation of the pharmacy is not feasible, a pharmacist shall be available on an "on call" basis.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 1961C**, IAB 4/15/15, effective 5/20/15]

657—7.3(155A) Reference library. A pharmacy shall maintain a reference library which is either printed or computer-accessed and which adequately meets the needs of the services provided and patients served. Examples of such references include:

1. A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.
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 drug 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 relating to specific patient populations served, such as pediatrics or geriatrics, or disease states treated, such as oncology or infectious disease.

[**ARC 2196C**, IAB 10/14/15, effective 11/18/15; **ARC 4267C**, IAB 1/30/19, effective 3/6/19]

657—7.4 Reserved.

657—7.5(124,155A) Security. The pharmacy shall be located in an area or areas that facilitate the provision of services to patients and shall be integrated with the facility's communication and transportation systems. The following conditions must be met to ensure appropriate control over drugs and chemicals in and under the control of the pharmacy:

7.5(1) *Pharmacy department security.* Policies and procedures shall identify measures to ensure the security of the pharmacy department, 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, including when the pharmacist is absent from the pharmacy department or absent from the facility pursuant to rule 657—7.6(155A).

7.5(2) *Security outside the pharmacy department.* Policies and procedures shall identify measures to ensure security in areas outside the pharmacy department where drugs, including controlled

substances, devices, drug records, and patient records are maintained or stored, including provisions for effective control against theft of, diversion of, or unauthorized access to such drugs and records.

7.5(3) *Authorized collection program.* Receptacles that are located in the hospital for the authorized collection of controlled substances shall be secured pursuant to 657—Chapter 10 and federal regulations for disposal of controlled substances.

7.5(4) *System security.* Electronic systems shall be secured to prevent unauthorized access. System login or access credentials issued to an authorized system user shall not be shared with or disclosed to any other individual.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9408B**, IAB 3/9/11, effective 4/13/11; **ARC 1308C**, IAB 2/5/14, effective 3/12/14; **ARC 2408C**, IAB 2/17/16, effective 3/23/16; **ARC 4267C**, IAB 1/30/19, effective 3/6/19]

657—7.6(155A) Pharmacist absence.

7.6(1) *Pharmacist absent from the pharmacy department.* A pharmacy's policies and procedures shall identify how the pharmacy will operate and be secured to prevent unauthorized access during times when the pharmacist may be absent from the pharmacy department but not absent from the facility. The policies and procedures shall also identify authorized activities of pharmacy staff in the pharmacy department during the absence of the pharmacist from the department in compliance with rules of the board.

a. *Remote pharmacy services.* Pursuant to rule 657—7.7(155A), the pharmacy may utilize the services of a remote pharmacist or pharmacy to provide pharmacist services to assist the pharmacy department while the on-site pharmacist is absent from the pharmacy department, such as when participating in clinical activities with facility staff and patients.

b. *Certified pharmacy technicians.* Pursuant to the pharmacy's policies and procedures, a certified pharmacy technician may be granted access to the pharmacy department to perform authorized technical functions. In the absence of a pharmacist, a certified pharmacy technician may only dispense, deliver, or distribute a drug, including a compounded preparation and controlled substance, when the drug is verified by a pharmacist, including by a remote pharmacist, except as authorized in an approved technician product verification program. A certified pharmacy technician may assist a licensed health care professional in locating a drug to meet the emergent needs of a patient but shall not provide final verification of the accuracy of the drug product obtained.

c. *Pharmacy support persons.* Pursuant to the pharmacy's policies and procedures, a pharmacy support person may be granted access to the pharmacy department to perform authorized nontechnical functions.

d. *Licensed health care professionals.* Pursuant to the pharmacy's policies and procedures, a licensed health care professional may be granted access to the pharmacy department to meet the emergent needs of a patient. A licensed health care professional may utilize the assistance of a certified pharmacy technician to locate a drug but shall not rely on the technician to verify the accuracy of the drug product obtained.

7.6(2) *Pharmacy department closed.* When the pharmacist is absent from the facility, the pharmacy department shall be closed and secured to prevent unauthorized access. The pharmacist in charge shall identify in policies and procedures the facility and pharmacy staff, by title or designation, who are authorized access to the pharmacy department and the specific activities that are authorized.

a. *Remote pharmacy services.* Pursuant to rule 657—7.7(155A), the pharmacy may utilize the services of a remote pharmacist or pharmacy to provide pharmacist services to the facility when the pharmacy is closed.

b. *Certified pharmacy technicians.* Pursuant to the pharmacy's policies and procedures, a certified pharmacy technician may be granted access to the pharmacy department to perform authorized technical functions. In the absence of a pharmacist, a certified pharmacy technician may only dispense, deliver, or distribute a drug, including a compounded preparation and controlled substance, when the drug is verified by a pharmacist, including by a remote pharmacist. During each period of time the certified pharmacy technician is working in the pharmacy without pharmacist supervision, the technician shall document the time worked and activities performed. The documentation shall be periodically reviewed by the

pharmacist in charge. A certified pharmacy technician may assist a licensed health care professional in locating a drug to meet the emergent needs of a patient but shall not provide the final verification of the accuracy of the drug obtained.

c. Pharmacy support persons. Pursuant to the pharmacy's policies and procedures, a pharmacy support person may be granted access to the pharmacy department to perform authorized nontechnical functions. During each period of time the pharmacy support person is working in the pharmacy without pharmacist supervision, the support person shall document the time worked and activities performed. The documentation shall be periodically reviewed by the pharmacist in charge.

d. Licensed health care professionals. Pursuant to the pharmacy's policies and procedures, a licensed health care professional may be granted access to the pharmacy department to meet the emergent needs of a patient. A licensed health care professional may utilize the assistance of a certified pharmacy technician to locate a drug but shall not rely on the technician to verify the accuracy of the drug product obtained. The pharmacy shall maintain documentation of such access and activities.

This rule is intended to implement Iowa Code sections 124.301, 147.76, 147.107, and 155A.33.

[**ARC 4267C**, IAB 1/30/19, effective 3/6/19; **ARC 5007C**, IAB 3/25/20, effective 4/29/20]

657—7.7(155A) Verification by remote pharmacist. A hospital pharmacy may contract with an Iowa-licensed pharmacy or pharmacist for remote pharmacist services, including medication order entry and review, final product verification, and provision of drug information. Pharmacies and pharmacists 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 on-site hospital pharmacy services and are not intended to eliminate the need for an on-site hospital pharmacy or pharmacist. The activities authorized by this rule are intended to increase the availability of the pharmacist for involvement in clinical patient care activities when the pharmacy is open or to continue the provision of pharmacy services when the pharmacy is closed. The hospital pharmacy shall maintain records that demonstrate the directing of pharmacist activities to additional clinical patient care activities, and those records shall be available for inspection by the board or its authorized agent.

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 pharmacist services identified in this chapter in compliance with this rule.

7.7(3) *Licenses required.* A pharmacy or pharmacist contracting with a hospital pharmacy to provide services pursuant to this rule shall maintain with the board a current Iowa pharmacy license or pharmacist license, respectively. 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) *Remote access requirements.* A pharmacist providing services from a remote location shall:

a. Have secure electronic access to the hospital's patient information system on which the pharmacist has been adequately trained,

b. Have access to the patient's health care team to discuss any concerns identified during the pharmacist's review of the patient's information or medication order,

c. Have secure access to any other electronic systems the pharmacist would otherwise have access to in the facility,

d. Have access to sufficient references to adequately meet the needs of the patients served, and

e. When involved in review or verification, be identified, by name or unique identifier and function performed, on the drug or device order.

[**ARC 9408B**, IAB 3/9/11, effective 4/13/11; **ARC 0502C**, IAB 12/12/12, effective 1/16/13; **ARC 4267C**, IAB 1/30/19, effective 3/6/19]

657—7.8(124,126,155A) Drug distribution and control. Policies and procedures governing drug distribution and control shall be established pursuant to rule 657—8.3(155A) 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.* Control and adequate quality assurance procedures needed to ensure that patients receive the correct drugs at the proper times shall be established pursuant to rule 657—8.3(155A).

a. Hospitals shall utilize a unit dose dispensing system pursuant to rule 657—22.1(155A). All drugs dispensed by the pharmacy 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) Established policies and procedures shall 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. All sterile and nonsterile compounded products shall be prepared in conformance with 657—Chapter 20.

7.8(2) *Medication orders.* Except to meet the emergent needs of a patient, no drug or device shall be dispensed or made available for patient administration prior to the issuance of a valid medication order and appropriate pharmacist review.

a. *Verbal order.* The use of verbal orders shall be minimized. All verbal orders shall be read back to the prescriber, and the read back shall be documented with or on the order.

b. *Written order not entered by prescriber.* If an individual other than the prescriber enters a medication order into an electronic medical record system from an original written medication order, a pharmacist shall review and verify the entry against the original written order before the drug is dispensed or made available for administration except for emergency use, when the pharmacy is closed, or as provided in rule 657—7.7(155A).

c. *Order entered when pharmacy closed.* When the pharmacy is closed and remote pharmacist services are not available, 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, except when a pharmacist entered the order, a pharmacist shall verify the entry against the original written medication order, if such written order exists, as soon as practicable.

d. *Abbreviations and chemical symbols on orders.* 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(3) *Stop order.* A policy concerning stop orders shall be established to ensure that medication orders are not inappropriately continued.

7.8(4) *Emergency drug supplies and floor stock.* Pursuant to policies and procedures, supplies of drugs for use in medical emergencies shall be immediately available. All drug storage areas within the facility shall be routinely inspected to ensure that no outdated or unusable items are available for administration and that all stock items are properly labeled and stored.

7.8(5) *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(6) *Drugs brought into the facility.* Established policies and procedures shall determine those circumstances when patient-owned drugs brought into the facility may be administered to the patient and shall identify procedures governing the use and security of drugs brought into the facility. Procedures shall address identification of the drug and methods for ensuring the integrity of the product prior to permitting its use. The use of patient-owned drugs shall be minimized to the greatest extent possible.

7.8(7) *Samples.* The use of drug samples within the institution shall be eliminated to the extent possible. Sample use is prohibited for hospital inpatient use. For the purposes of this subrule, "samples" shall not include initiation doses provided by a manufacturer's long-acting antipsychotic medication initiation program.

7.8(8) *Investigational drugs.* If investigational drugs are used in the facility:

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

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

7.8(9) *Hazardous drugs and chemicals.* Policies and procedures for handling drugs and chemicals that are known occupational hazards shall be established pursuant to rule 657—8.3(155A). The procedures shall maintain the integrity of the drug or chemical and protect facility personnel.

7.8(10) *Leave and discharge meds.* Labeling of medications for a patient on leave from the facility for a period in excess of 24 hours or being discharged from the facility shall comply with 657—subrule 6.10(1).

7.8(11) *Own-use outpatient prescriptions.* If the hospital pharmacy dispenses own-use outpatient prescriptions, the pharmacist shall comply with all requirements of 657—Chapter 6 except rule 657—6.1(155A).

7.8(12) *Influenza and pneumococcal vaccines.* As authorized by federal law, a patient-specific medication order shall not be required prior to administration to an adult patient of influenza and pneumococcal vaccines pursuant to physician-approved facility policy and after the patient has been assessed for contraindications. Administration shall be recorded in the patient's medical record.

7.8(13) *Accountability of stock supply.* An individual who administers a controlled substance from a non-patient-specific stock supply in a facility 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 or unique electronic signature or identification of a witnessing licensed health care practitioner. Distribution records for non-patient-specific floor-stocked controlled substances shall include the following information:

a. Patient's name;

b. Prescriber who ordered the drug;

c. Drug name, strength, dosage form, and quantity;

d. Date and time of administration;

e. Signature or unique electronic signature of the individual administering the controlled substance;

f. Returns to the pharmacy;

g. Waste, which is required to be witnessed and cosigned by another licensed health care practitioner.

[**ARC 8170B**, IAB 9/23/09, effective 10/28/09; **ARC 9911B**, IAB 12/14/11, effective 1/18/12; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 2197C**, IAB 10/14/15, effective 11/18/15; **ARC 4267C**, IAB 1/30/19, effective 3/6/19]

657—7.9(124,155A) Drug information. Established policies and procedures shall include the provision to the facility's staff and patients of accurate, comprehensive information about drugs and their use. The pharmacy shall serve as the facility's center for drug information.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 4267C**, IAB 1/30/19, effective 3/6/19]

657—7.10(124,155A) Ensuring rational drug therapy. An important aspect of pharmaceutical services is that of maximizing rational drug use. Policies and procedures for ensuring the quality of drug therapy shall be established pursuant to rule 657—8.3(155A). For the purpose of this rule, "professional pharmacy staff" means the professional employees of the pharmacy, including pharmacists, pharmacy technicians, and pharmacist-interns.

7.10(1) *Patient profile.* The pharmacy shall maintain for each patient receiving care at the hospital a patient profile, to include but not be limited to drug history. Sufficient patient information to ensure meaningful and effective patient care shall be collected, maintained, and reviewed by professional pharmacy staff pursuant to policies and procedures. Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice. Upon review of a patient's

current clinical profile, the pharmacist shall directly communicate any suggested changes to the patient's health care team.

7.10(2) *Adverse drug events.* Established policies and procedures shall include a mechanism for the reporting of adverse drug events that occur in the facility which events are reviewed by the facility's established quality control committee. The pharmacist shall be informed of all reported adverse drug events occurring in the facility. Adverse drug events include but are not limited to adverse drug reactions and medication errors.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 4267C**, IAB 1/30/19, effective 3/6/19]

657—7.11(124,126,155A) Outpatient services. No prescription drugs shall be dispensed from the hospital pharmacy to patients treated in a hospital outpatient setting. If a need is established for the dispensing of a prescription drug to an outpatient, a prescription shall be issued to be filled at a pharmacy of the patient's choice.

7.11(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Emergency department patient" means a patient who is examined and evaluated in the emergency department.

"Outpatient" means a patient who was examined and evaluated by a prescriber who determined the patient's need for the administration of a drug or device, when the patient presents to the hospital outpatient setting with a prescription or order for administration of a drug or device. "Outpatient" does not include an emergency department patient.

"Outpatient medication order" means an order issued by a prescriber pursuant to rules of the board for administration of a drug or device. An outpatient medication order may authorize continued or periodic administration of a drug or device for a period of time and frequency determined by the prescriber or by hospital policy, not to exceed legal limits for the refilling of a prescription drug order.

7.11(2) *Administration in the outpatient setting.* Drugs shall be administered only to outpatients who have been examined and evaluated by a prescriber who determined the patient's need for the drug therapy ordered.

a. Accountability. Established policies and procedures shall include a system of drug control and accountability in the outpatient setting. The system shall ensure accountability of drugs incidental to outpatient nonemergency therapy or treatment. Drugs shall be administered only in accordance with the system.

b. Controlled substances. Controlled substances maintained in the outpatient setting are kept for use by or at the direction of prescribers for the nonemergency therapy or treatment of outpatients. In order to have a controlled substance administered, a patient shall be examined in the outpatient setting or in an alternate practice setting or office by a prescriber who shall determine the patient's need for the drug. If the patient is examined in a setting other than the outpatient setting, the prescriber shall issue a prescription or order for administration of the drug in the hospital outpatient setting.

c. Outpatient medication orders. A prescriber may authorize, by outpatient medication order, the periodic administration of a drug to an outpatient.

(1) Schedule II controlled substance. An outpatient medication order for administration of a Schedule II controlled substance shall be issued pursuant to federal regulation and board rules and, except as provided in rule 657—10.29(124) regarding the issuance of multiple Schedule II prescriptions, may authorize the administration of an appropriate amount of the prescribed substance for a period not to exceed 90 days from the date ordered.

(2) Schedule III, IV, or V controlled substance. An outpatient medication order for administration of a Schedule III, IV, or V controlled substance shall be issued pursuant to federal regulation and board rules and may be authorized for a period not to exceed six months from the date ordered.

(3) Noncontrolled substance. An outpatient medication order for administration of a noncontrolled prescription drug may be authorized for a period not to exceed 18 months from the date ordered.

7.11(3) *Samples.* 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 facility's appropriate patient care committee, subject to oversight by the pharmacy.

[**ARC 8909B**, IAB 6/30/10, effective 8/4/10; **ARC 0243C**, IAB 8/8/12, effective 9/12/12; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4267C**, IAB 1/30/19, effective 3/6/19]

657—7.12(124,126,155A) Drugs in the emergency department. Drugs maintained in the emergency department are kept for use by or at the direction of prescribers in the emergency department. Drugs shall be administered or dispensed only to emergency department patients. For the purposes of this rule, "emergency department patient" means a patient who is examined and evaluated in the emergency department and includes the partner or partners of a patient treated pursuant to Iowa Code section 139A.41.

7.12(1) *Accountability.* Established policies and procedures shall include a system of drug control and accountability in the emergency department. The system shall identify drugs of the nature and type to meet the emergency needs of patients. Drugs shall be administered or dispensed only in accordance with the system.

7.12(2) *Controlled substances.* Controlled substances maintained in the emergency department are kept for use by or at the direction of prescribers in the emergency department.

a. In order to receive a controlled substance, a patient shall be examined in the emergency department by a prescriber who shall determine the need for the drug. It is not permissible under state and federal regulations for a prescriber to see a patient outside the emergency department setting, or talk to the patient on the telephone, and then proceed to call the emergency department and order the administration of a stocked controlled substance upon the patient's arrival at the emergency department except as provided in paragraph 7.12(2)*"c"* or *"d."*

b. 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.

c. 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 7.12(2)*"a,"* the emergency department nurse may examine the patient in the emergency department 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 at the emergency department. As soon as possible, the prescriber shall examine the patient in the emergency department and determine the patient's further treatment needs.

d. In an emergency situation when a health care practitioner authorized to prescribe controlled substances examines a patient in the prescriber's office and determines a need for the administration of a controlled substance, and regardless of the provisions of paragraph 7.12(2)*"a,"* the prescriber may direct the patient to present to the emergency department for the administration of a controlled substance for which the prescriber has issued a prescription in compliance with federal regulation and board rules. As soon as possible, the prescriber shall examine the patient in the emergency department and determine the patient's further treatment needs.

7.12(3) *Drug dispensing.* Only a pharmacist or prescriber may dispense any drugs to an emergency department patient pursuant to the provisions of this rule.

a. *Responsibility.* Pursuant to rule 657—8.3(155A), policies and procedures shall be established to ensure the accuracy and labeling of prepackaged drugs and accurate records of dispensing of drugs from the emergency department shall be maintained.

(1) Except as provided in subrule 7.12(4), drugs dispensed to an emergency department patient may be dispensed in quantities not to exceed a 72-hour supply or the minimum quantity in suitable containers, except that an authorized supply of a drug provided through the department of public health may be dispensed for the treatment of a victim of sexual assault. Prepackaged drugs shall be prepared pursuant to the requirements of rule 657—22.3(126).

(2) Drugs dispensed pursuant to this paragraph shall be appropriately labeled as required in paragraph 7.12(3)*"b,"* including necessary auxiliary labels.

b. *Prescriber responsibility.* Except as provided in subrule 7.12(4), a prescriber who authorizes the dispensing of a prescription drug to an emergency department patient is responsible for the accuracy of the dispensed drug and for the accurate completion of label information pursuant to this paragraph, including when any portion of the dispensing process is delegated to a licensed nurse under the supervision of the prescriber.

(1) Except as provided in subrule 7.12(4), at the time of delivery of the drug the prescriber shall be responsible for ensuring that the dispensing container bears a label with at least the following information:

1. Name and address of the hospital;
2. Date dispensed;
3. Name of prescriber;
4. Name of patient, except when the drug is dispensed for one or more unnamed partners receiving expedited partner therapy pursuant to Iowa Code section 139A.41;
5. Directions for use; and
6. Name, quantity, and strength of drug.

(2) Except as provided in subrule 7.12(4), the prescriber, or a licensed nurse under the supervision of the prescriber, shall give the appropriately labeled, packaged drug to the patient or patient's caregiver. The prescriber, or a licensed nurse under the supervision of the prescriber, 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 issue a prescription for the additional quantities to be filled at a pharmacy of the patient's choice.

7.12(4) *Use of an outpatient point-of-care automated dispensing system (OPCADS).* 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 utilize an outpatient point-of-care automated dispensing system (OPCADS) in the emergency department only as provided by this subrule. For the purpose of this rule, an OPCADS is a secure dispensing system which contains prepackaged medications verified by authorized pharmacy personnel for dispensing to a patient upon issuance of a valid prescription by a prescriber. The OPCADS shall be owned by the facility, shall be operated under the facility's hospital pharmacy license, shall not be issued a separate general or limited use pharmacy license, and shall not provide any financial incentive for use to any prescriber employed or under contract with the emergency department.

a. Persons with access to the OPCADS for the purposes of stocking, inventory, and monitoring shall be limited to pharmacists, pharmacy technicians, and pharmacist-interns.

b. The OPCADS shall be used only in the emergency department for the benefit of patients examined or treated in the emergency department when the benefit to the patient outweighs the burden on the patient to obtain the medication elsewhere.

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

d. The stock of drugs maintained and dispensed utilizing the OPCADS 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 OPCADS shall be appropriately labeled as provided in 657—paragraphs 6.10(1)*"a"* through *"g."*

f. Prior to authorizing the dispensing of a drug utilizing the OPCADS, the prescriber shall offer to issue the patient a prescription that may be filled at a pharmacy of the patient's choice.

g. During consultation with the patient or the patient's caregiver, the prescriber or licensed nurse under the supervision of the prescriber shall clearly explain the appropriate use of the drug supplied. If additional quantities of the drug are required to complete the needed course of treatment, the prescriber shall issue a prescription for the additional quantity to be filled at a pharmacy of the patient's choice.

h. The pharmacy shall, in conjunction with the emergency department, implement policies and procedures to ensure that a patient utilizing the OPCADS has been positively identified.
[**ARC 8909B**, IAB 6/30/10, effective 8/4/10; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 4267C**, IAB 1/30/19, effective 3/6/19; **ARC 4903C**, IAB 2/12/20, effective 3/18/20]

657—7.13(124,155A) Records. Every 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 authorized agent for at least two years from the date of such record unless a longer retention period is specified for the particular record.

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

a. Patient name and identification number;

b. Drug name, strength, and dosage form;

c. Directions for use;

d. Date ordered;

e. Prescriber's signature or electronic signature or that of the prescriber'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.

7.13(4) *Storage of records.* Original hard-copy records shall be maintained by the pharmacy for a minimum of two years from the date of the record in accordance with this subrule.

a. Records shall be maintained within the pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the pharmacy department, including at a remote location, if the pharmacy has retained an electronic copy of the records in the pharmacy that is immediately available and if the original records are available within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

b. Records more than 12 months old may be maintained in a secure storage area outside the pharmacy department, including at a remote location, if the records are retrievable within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.
[**ARC 4267C**, IAB 1/30/19, effective 3/6/19; **ARC 5007C**, IAB 3/25/20, effective 4/29/20]

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 124.308, 126.10, 126.11, 155A.6A, 155A.6B, 155A.7, 155A.13, 155A.15, 155A.27, 155A.28, 155A.31 through 155A.36, 155A.38, 155A.41, 155A.43, and 155A.44.

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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 purpose of this chapter is to establish the minimum standards of pharmacy practice for the activities identified in this chapter. The requirements of these rules shall apply to all Iowa-licensed pharmacists, other registered pharmacy personnel, and all pharmacies, including owners, providing the services addressed in this chapter to patients in Iowa. These rules are in addition to rules of the board relating to specific types of pharmacy licenses issued by the board unless otherwise indicated by rule.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.2(155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Confidential information" means information accessed or maintained by the pharmacy in the patient's or the pharmacy's records which contains personally identifiable information that could be used to identify the patient. "Confidential information" 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.

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

"Pharmacy support person" or *"PSP"* means a person, other than a member of the professional pharmacy staff, registered with the board who may perform nontechnical duties assigned by a supervising pharmacist under the pharmacist's responsibility and supervision.

"Professional pharmacy staff" shall mean the professional employees of the pharmacy, including pharmacists, pharmacy technicians, and pharmacist-interns.

This rule is intended to implement Iowa Code chapter 155A.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.3(155A) Responsible parties.

8.3(1) *Pharmacist in charge.* One professionally competent, legally qualified pharmacist in charge in each pharmacy shall work cooperatively with the pharmacy, by and through its owner or license holder, and with all staff pharmacists to ensure 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. A part-time pharmacist in charge has the same obligations and responsibilities as a full-time pharmacist in charge.

8.3(2) *Pharmacy.* Each pharmacy, by and through its owner or license holder, shall work cooperatively with the pharmacist in charge and with all staff pharmacists to ensure 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. The pharmacy, by and through its owner or license holder, shall be responsible for employing a professionally competent, legally qualified pharmacist in charge. The pharmacy, by and through its owner or license holder, may be held responsible for unethical conduct or practices of any of the pharmacy staff.

8.3(3) *Pharmacy and pharmacist in charge.* The pharmacist in charge and the pharmacy, by and through its owner or license holder, shall share responsibility for, at a minimum, the following:

a. Ensuring that the pharmacy employs an adequate number of qualified personnel commensurate with the size and scope of services provided by the pharmacy.

b. Ensuring the availability of any equipment and references necessary for the particular practice of pharmacy.

c. 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, including controlled substances, devices, and pharmacy records, and to support the operations of the pharmacy.

d. Ensuring that the license, registration, or certification of each professional pharmacy staff member and the registration of each pharmacy support person are maintained in current and active status.

8.3(4) *Pharmacist in charge and staff pharmacists.* The pharmacist in charge and staff pharmacists shall share responsibility for, at a minimum, the following:

a. Ensuring that a pharmacist performs prospective drug use review as specified in rule 657—8.21(155A).

b. Ensuring that a pharmacist or pharmacist-intern provides patient counseling as specified in rule 657—6.14(155A).

c. Dispensing drugs to patients, including the packaging, preparation, compounding, and labeling functions performed by pharmacy personnel.

d. Delivering drugs to the patient or the patient's agent.

e. Ensuring that patient medication records are maintained as specified in rule 657—6.13(155A).

f. Training and supervising pharmacist-interns, pharmacy technicians, pharmacy support persons, and other pharmacy employees.

g. Procuring and storing prescription drugs and devices and other products dispensed from the pharmacy.

h. Distributing and disposing of drugs from the pharmacy.

i. 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.

j. 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.

8.3(5) *Pharmacy, pharmacist in charge, and staff pharmacists.* The pharmacy, by and through its owner or license holder, the pharmacist in charge, and all staff pharmacists shall share responsibility for, at a minimum, the following:

a. Establishing and periodically reviewing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and complying (by the pharmacist in charge and staff pharmacists) with policies and procedures for all operations of the pharmacy. The policies and procedures shall identify the frequency of review.

b. Establishing and maintaining effective controls against the theft or diversion of prescription drugs, including controlled substances, and records for such drugs.

c. Establishing (by the pharmacy and the pharmacist in charge), implementing (by the pharmacist in charge), and utilizing (by the pharmacist in charge and staff pharmacists) an ongoing, systematic program of continuous quality improvement for achieving performance enhancement and ensuring the quality of pharmaceutical services.

8.3(6) *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 pharmacy support persons.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 1576C**, IAB 8/20/14, effective 9/24/14; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.4(155A) Pharmacist identification and staff logs.

8.4(1) *Display of pharmacist license.* During any period a pharmacist is working in a pharmacy, each pharmacist shall display, in a position visible to the public, an original license to practice pharmacy in Iowa. 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) *Registration maintained of pharmacy personnel.* Each pharmacist-intern, pharmacy technician, and pharmacy support person shall maintain current registration with the board. The registration certificate or a copy of the registration certificate shall be readily retrievable upon request of the board or its authorized agent.

8.4(3) *Identification codes.* A permanent log of the initials or identification code identifying by name each pharmacist, pharmacist-intern, pharmacy technician, and pharmacy support person 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, pharmacy technician, and pharmacy support person can be identified.

8.4(4) *Temporary or intermittent pharmacy staff.* The pharmacy shall maintain a log of all pharmacists, pharmacist-interns, pharmacy technicians, and pharmacy support persons 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, pharmacy technician, and pharmacy support person 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(5) *Identification.* While on duty, pharmacy personnel shall wear visible identification that clearly identifies the person by licensed or registered title and includes at least the person's first name.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9409B**, IAB 3/9/11, effective 4/13/11; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

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 pursuant to rule 657—8.3(155A). Space and equipment shall be available in an amount and type to provide secure, environmentally controlled storage of drugs.

8.5(1) *Refrigeration.* The pharmacy shall maintain one or more refrigeration units, unless the pharmacy does not stock refrigerated items. The pharmacy shall document verification that the temperature of the refrigerator is maintained within a range compatible with the proper storage of drugs requiring refrigeration. If the temperature is manually or visually verified, a record of minimum daily verification shall be maintained.

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.* A 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—7.5(124,155A). To ensure that secure closure, 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.

8.5(4) *Remodel or relocation—inspection.* A pharmacy planning to remodel or relocate a licensed pharmacy department on or within the premises currently occupied by the pharmacy department, or a pharmacy intending to remodel or install a sterile compounding facility or equipment, shall provide written notification to the board at least 30 days prior to commencement of the remodel, pharmacy relocation, or sterile compounding installation. The board may require on-site inspection of the facility, equipment, or pharmacy department prior to or during the pharmacy's remodel, relocation, or opening. The board may also require on-site inspection of a temporary pharmacy location intended to be utilized during the remodel, construction, or relocation of the pharmacy department.

8.5(5) *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. Animals shall not be allowed within a licensed pharmacy unless that pharmacy is exclusively providing services for the treatment of animals or unless the animal is a service animal or service-animal-in-training as defined in Iowa Code section 216C.1A.

8.5(6) *Light, ventilation, temperature, and humidity.* The pharmacy shall be properly lighted and ventilated. 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 and the pharmacy, by and through its owner or license holder, shall share the responsibility for ensuring 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. Established policies and procedures shall include a method to calibrate and verify the accuracy of the counting device. The pharmacy shall, at least quarterly, verify the accuracy of the device and maintain a dated record identifying the individual who performed the quarterly verification.

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

8.5(10) *Health of personnel.* The pharmacist in charge or supervising pharmacist shall ensure that pharmacy personnel experiencing any health condition that may have an adverse effect on drug products or may pose a health or safety risk to others be prohibited from working in the pharmacy until such health condition is sufficiently resolved. All personnel who normally assist the pharmacist shall 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.

8.5(11) *Hazardous drugs.* The pharmacy shall ensure pharmacy personnel and patients are adequately protected from unnecessary exposure to hazardous drugs. As of December 1, 2019, the pharmacy shall be in compliance with United States Pharmacopeia (USP) General Chapter 800 for handling hazardous drugs. A pharmacy engaged in compounding of hazardous drugs may request delayed compliance for specific requirements in USP General Chapter 800 pertaining to compounding, in accordance with rule 657—20.5(126,155A).

[**ARC 8671B**, IAB 4/7/10, effective 5/12/10; **ARC 0503C**, IAB 12/12/12, effective 1/16/13; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 2408C**, IAB 2/17/16, effective 3/23/16; **ARC 3858C**, IAB 6/20/18, effective 7/25/18; **ARC 4267C**, IAB 1/30/19, effective 3/6/19; **ARC 4454C**, IAB 5/22/19, effective 6/26/19; **ARC 5348C**, IAB 12/30/20, effective 2/3/21]

657—8.6(155A) Health of personnel. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

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 an Iowa-licensed distributor or, on a limited basis, from another licensed pharmacy or licensed practitioner located in the United States.

8.7(2) *Manner of storage.* Drugs and devices shall be stored in a manner to protect their identity and integrity.

8.7(3) *Storage temperatures.* All drugs and devices shall be stored at the proper temperature as provided in manufacturer labeling. In the absence of a specific temperature range, the pharmacy shall defer to storage conditions identified in United States Pharmacopeia chapter 659.

8.7(4) *Product recall.* There shall be a system for removing from use, including unit dose, any drugs and devices subjected to a product recall.

8.7(5) *Outdated 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.

8.7(6) *Records.* All pharmacies shall maintain supplier invoices of prescription drugs and controlled substances upon which the actual date of receipt of the drugs by the pharmacist or other responsible individual is clearly recorded. All pharmacies shall maintain supplier credit memos. Pharmacy records

of invoices and credit memos shall be maintained for at least two years from the date of the record. If the original supplier invoice or credit memo is received electronically, hard-copy record is not required.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.8(124,155A) Out-of-date drugs or devices. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

657—8.9(124,155A) Records storage. Every 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 record or the date of last activity on the record unless a longer retention period is specified for the particular record.

8.9(1) *Records less than 12 months old.* Records shall be maintained within the licensed pharmacy department for a minimum of 12 months, except as provided herein. Pharmacy records less than 12 months old may be stored in a secure storage area outside the licensed pharmacy department, including at a remote location, if the pharmacy has retained electronic copies of the records in the pharmacy that are immediately available and if the original records are available within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.

8.9(2) *Records more than 12 months old.* Records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department, including at a remote location, if the records are retrievable within 72 hours of a request by the board or its authorized agent, unless such remote storage is prohibited under federal law.
[**ARC 8539B**, IAB 2/24/10, effective 4/1/10; **ARC 3858C**, IAB 6/20/18, effective 7/25/18; **ARC 5007C**, IAB 3/25/20, effective 4/29/20]

657—8.10 Reserved.

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

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

8.11(2) *Unethical conduct.*

a. A pharmacy, pharmacist, pharmacist-intern, technician, or support person shall not participate in any of the following types of unethical conduct:

(1) Any activity that negates a patient's freedom of choice of pharmacy services.

(2) Providing prescription blanks or forms bearing the pharmacy's name or other means of identification to any person authorized to prescribe, except that a hospital may make prescription blanks or forms bearing the hospital pharmacy's name or other means of identification available to hospital staff prescribers, emergency department prescribers, and prescribers granted hospital privileges for the prescribers' use during practice at or in the hospital.

(3) Any financial arrangement or transaction that would violate federal healthcare fraud, waste, and abuse laws, including but not limited to the Stark Law, the False Claims Act, and the Anti-Kickback Statute.

b. A purchasing pharmacist or pharmacy shall not engage in any activity or include in any agreement with a selling pharmacist or pharmacy any provision that would prevent or prohibit the prior notifications required in subrule 8.35(7).

8.11(3) *Discrimination.* A pharmacy, pharmacist, pharmacist-intern, technician, or pharmacy support person shall not 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(4) *Unprofessional conduct or behavior.* A pharmacy, pharmacist, pharmacist-intern, technician, or pharmacy support person shall not engage in unprofessional behavior in connection with the practice of pharmacy. 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, theft, and the refusal to provide reasonable information or answer reasonable questions for the benefit of the patient.
[**ARC 9526B**, IAB 6/1/11, effective 7/6/11; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.12(126,147) Advertising. Prescription drug information, including price, 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 shall 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 board.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

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 child and dependent adult abuse record checks 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 request that the department of public safety perform 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 request that the department of human services perform a child and dependent adult abuse record 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.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.14(155A) Training and utilization of registered pharmacy staff. Pursuant to rule 657—8.3(155A), all Iowa-licensed pharmacies utilizing pharmacist-interns, pharmacy technicians, or pharmacy support persons shall have written policies and procedures for the training and utilization of

pharmacist-interns, pharmacy technicians, and pharmacy support persons appropriate to the practice of pharmacy at that licensed location. Training shall be documented and maintained by the pharmacy for at least two years from the last date of employment or internship and shall be available for inspection by the board or its authorized agent.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.15(155A) Delivery of prescription drugs and devices. A prescription order may be delivered to a patient at any location licensed as a pharmacy. Alternatively, a pharmacy may use the mail, a common carrier, or personal delivery to deliver a prescription order to any location requested by the patient. A pharmacy that delivers prescription orders by one or more alternate methods shall have policies and procedures to ensure patient confidentiality, prescription order accountability, and proper storage of prescription orders during delivery. When counseling is required pursuant to rule 657—6.14(155A), oral counseling shall be provided before the prescription order is delivered to the patient. Documentation of the delivery of prescription orders shall be maintained by the pharmacy for at least two years from the date of delivery. The term "patient" includes the patient and the patient's authorized representatives.
[**ARC 5007C**, IAB 3/25/20, effective 4/29/20]

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

8.16(1) *Release of confidential information.* Confidential information 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(2) *Exceptions.* Nothing in this rule shall prohibit a pharmacist 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 or pursuant to subrule 8.35(7) when the pharmacy is discontinuing operations.

b. Providing the patient with a copy of a nonrefillable prescription that is clearly marked as a copy and not to be filled.

c. Providing drug therapy information to authorized practitioners for their patients.

d. Disclosing information necessary for the processing of third-party payer claims on behalf of the patient.

8.16(3) *Record disposal.* Disposal of any materials containing or including patient-specific or confidential information shall be conducted in a manner to preserve patient confidentiality.
[**ARC 9526B**, IAB 6/1/11, effective 7/6/11; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.17 Reserved.

657—8.18(124,155A) Electronic prescription mandate. Beginning January 1, 2020, all prescriptions shall be transmitted electronically to a pharmacy pursuant to rule 657—21.6(124,155A), except as provided in rule 657—21.8(124,155A). A pharmacist who receives a written, oral, or facsimile prescription shall not be required to verify that the prescription is subject to an exception provided in rule 657—21.8(124,155A) and may dispense a prescription drug pursuant to an otherwise valid written, oral, or facsimile prescription pursuant to rule 657—8.19(124,126,155A).
[**ARC 4580C**, IAB 7/31/19, effective 9/4/19]

657—8.19(124,126,155A) Manner of issuance of a prescription drug or medication order. A prescription drug order or medication order that is issued prior to January 1, 2020, or that is exempt

from the electronic prescription mandate pursuant to rule 657—21.8(124,155A) may be transmitted from a prescriber or a prescriber's agent to a pharmacy in written form, orally including telephone voice communication, by facsimile transmission as provided in rule 657—21.7(124,155A), or by electronic transmission in accordance with applicable federal and state laws, rules, and regulations. 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—21.6(124,155A).

8.19(1) *Requirements for a prescription.* A valid prescription drug order shall be based on a valid patient-prescriber relationship except as provided in subrule 8.19(7) for epinephrine auto-injectors and in subrule 8.19(8) for opioid antagonists.

a. Written, electronic, or facsimile prescription. In addition to the electronic prescription application and pharmacy prescription application requirements of this rule, a written, electronic, or facsimile prescription shall include:

(1) The date issued.

(2) The name and address of the patient except as provided in subrule 8.19(7) for epinephrine auto-injectors, subrule 8.19(8) for opioid antagonists, or subrule 8.19(9) for expedited partner therapy.

(3) The name, strength, and quantity of the drug or device prescribed.

(4) The name and address of the prescriber and, if the prescription is for a controlled substance, the prescriber's DEA registration number.

(5) The written or electronic signature of the prescriber.

b. Written prescription. In addition to the requirements of paragraph 8.19(1)*"a,"* a written prescription shall be manually signed, with ink or indelible pencil, by the prescriber. The requirement for manual signature shall not apply when an electronically prepared and signed prescription for a noncontrolled substance is printed on security paper as provided in 657—paragraph 21.6(2)*"b."*

c. Facsimile prescription. In addition to the requirements of paragraph 8.19(1)*"a,"* a prescription transmitted via facsimile shall include:

(1) The identification number of the facsimile machine used to transmit the prescription to the pharmacy.

(2) The time and date of transmission of the prescription.

(3) The name, address, telephone number, and facsimile number of the pharmacy to which the prescription is being transmitted.

(4) If the prescription is for a controlled substance and in compliance with DEA regulations, the manual signature of the prescriber.

d. Electronic prescription. In addition to the requirements of paragraph 8.19(1)*"a,"* an electronically prepared prescription for a controlled or noncontrolled prescription drug or device that is electronically transmitted to a pharmacy shall include the prescriber's electronic signature, except as provided herein.

(1) An electronically prepared prescription for a controlled substance that is printed out or faxed by the prescriber or the prescriber's agent shall be manually signed by the prescriber.

(2) The prescriber shall ensure that the electronic prescription application used to prepare and transmit the electronic prescription complies with applicable state and federal laws, rules, and regulations regarding electronic prescriptions.

(3) The prescriber or the prescriber's agent shall provide verbal verification of an electronic prescription upon the request of the pharmacy.

(4) An electronic prescription for a noncontrolled prescription drug or device that is transmitted by an authorized agent shall not be required to contain the prescriber's electronic signature.

8.19(2) *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, rules, and regulations. In exercising professional judgment, the prescriber and the pharmacist shall take adequate measures to guard against the diversion of prescription drugs and controlled substances through prescription forgeries.

8.19(3) *Transmitting agent.* The prescriber may authorize an agent to transmit to the pharmacy a prescription drug order or medication order orally, by facsimile transmission, or by electronic

transmission provided that the first and last names and title of the transmitting agent are 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, except as provided in paragraph 8.19(1)*"d."* If transmitted by the prescriber's agent, the first and last names and title of the transmitting agent shall be included in the order. If the prescription is for a controlled substance and is written or printed from an electronic prescription application, the prescription shall be manually signed by the prescriber. An electronically prepared prescription shall not be electronically transmitted to the pharmacy if the prescription has been printed prior to the electronic transmission. An electronically prepared and electronically transmitted prescription that is printed following the electronic transmission shall be clearly labeled as a copy, not valid for dispensing.

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 professional pharmacy staff through oral communication, in writing, by facsimile transmission, or by electronic transmission initiated by or directed by the prescriber.

(1) If the transmission is completed by the prescriber's agent and the first and last names and title of the transmitting agent are 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 8.19(3)*"a."*

8.19(4) *Receiving agent.* Regardless of the means of transmission to a pharmacy, only professional pharmacy staff shall be authorized to receive a new prescription drug or medication order from a prescriber or the prescriber's agent. A technician trainee may receive a refill or renewal order from a prescriber or the prescriber's agent only if the technician's supervising pharmacist has authorized that function.

8.19(5) *Legitimate purpose.* The pharmacy and professional pharmacy staff shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by a prescriber acting in the usual course of the prescriber'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.

8.19(6) *Refills.* A refill is one or more dispensings of a prescription drug or device that result in the patient's receipt of the quantity authorized by the prescriber for a single fill as indicated on the prescription drug order.

a. Noncontrolled prescription drug or device. 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.

b. Controlled substance. A prescription for a Schedule III, IV, or V controlled substance may authorize no more than 5 refills within 6 months following the date on which the prescription is issued.

8.19(7) *Epinephrine auto-injector prescription issued to school or facility.* A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more epinephrine auto-injectors in the name of a facility as defined in Iowa Code subsection 135.185(1), a school district, or an accredited nonpublic school. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the facility, the school district, or the accredited nonpublic school in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy's patient profile and record of dispensing of a prescription issued pursuant to this subrule shall be maintained in the name of the facility, school district, or accredited nonpublic school to which the prescription was issued and the drug was dispensed.

b. The label affixed to an epinephrine auto-injector dispensed pursuant to this subrule shall identify the name of the facility, school district, or accredited nonpublic school to which the prescription is dispensed.

8.19(8) *Opioid antagonist prescription issued to law enforcement, fire department, or service program.* A physician, an advanced registered nurse practitioner, or a physician assistant may issue a prescription for one or more opioid antagonists in the name of a law enforcement agency, fire department, or service program pursuant to Iowa Code section 147A.18 and rule 657—39.7(135,147A). The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall be issued in the name and address of the law enforcement agency, fire department, or service program in lieu of the name and address of a patient. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

a. The pharmacy's patient profile and record of dispensing of an opioid antagonist pursuant to this subrule shall be maintained in the name of the law enforcement agency, fire department, or service program to which the prescription was issued and the drug was dispensed.

b. The label affixed to an opioid antagonist dispensed pursuant to this subrule shall identify the name of the law enforcement agency, fire department, or service program to which the prescription is dispensed and shall be affixed such that the expiration date of the drug is not rendered illegible.

8.19(9) *Expedited partner therapy.* Pursuant to Iowa Code section 139A.41, a physician, physician assistant, or advanced registered nurse practitioner may issue a prescription to one or more sexual partners of an infected patient for an oral antibiotic intended to treat a sexually transmitted chlamydia or gonorrhea infection. The prescription shall comply with all requirements of subrule 8.19(1) as applicable to the form of the prescription except that the prescription shall not be required to contain the patient name and address. The prescription shall indicate the antibiotic is being issued for the purpose of expedited partner therapy. Provisions requiring a preexisting patient-prescriber relationship shall not apply to a prescription issued pursuant to this subrule.

[**ARC 8171B**, IAB 9/23/09, effective 10/28/09; **ARC 9912B**, IAB 12/14/11, effective 1/18/12; **ARC 2414C**, IAB 2/17/16, effective 3/23/16; **ARC 2827C**, IAB 11/23/16, effective 11/3/16; **ARC 3858C**, IAB 6/20/18, effective 7/25/18; **ARC 4580C**, IAB 7/31/19, effective 9/4/19; **ARC 4903C**, IAB 2/12/20, effective 3/18/20]

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, any remaining prescription refills may be dispensed at the discretion of the pharmacist for a suitable amount of time so that the patient can establish care with a new provider and a new order can be issued. In determining the duration of which prescriptions may be dispensed, the pharmacist shall consider the patient's health care status and access to health care services.

[**ARC 3639C**, IAB 2/14/18, effective 3/21/18]

657—8.21(155A) Prospective drug use review.

8.21(1) 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:

a. Overutilization or underutilization;

b. Therapeutic duplication;

c. Drug-disease contraindications;

d. Drug-drug interactions;

e. Incorrect drug dosage or duration of drug treatment;

f. Drug-allergy interactions;

g. Clinical abuse/misuse;

h. 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. Information that shall be

obtained for the purpose of drug utilization review includes, but is not limited to, a complete list of prescription and nonprescription medications being used by the patient, patient allergies, and patient disease states. The collection of patient information to be used for drug utilization review may be delegated to a pharmacy technician or pharmacist-intern. The review and assessment of patient records shall not be delegated to pharmacy technicians or pharmacy support persons but may be delegated to registered pharmacist-interns under the direct supervision of the pharmacist.

8.21(2) A pharmacist shall be exempt from the requirements of subrule 8.21(1) when dispensing a prescription issued to an unnamed patient for an oral antibiotic pursuant to Iowa Code section 139A.41.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18; **ARC 4903C**, IAB 2/12/20, effective 3/18/20; **ARC 5350C**, IAB 12/30/20, effective 2/3/21]

657—8.22(155A) Notification of interchangeable biological product selection. Pursuant to Iowa Code section 155A.32, when a pharmacist substitutes a biological product that is an interchangeable biological product for the biological product prescribed, the pharmacist or pharmacist's designee shall, within five business days of dispensing the biological product, communicate to the prescriber the name and manufacturer of the biological product dispensed unless the prescription information has been entered into an electronic record system, such as an electronic medical record, electronic prescribing system, pharmacy benefit management system, or a pharmacy record to which the prescriber has access. The manner of communication to the prescriber may be via telephone, facsimile, electronic transmission, or other prevailing means.

This rule is intended to implement Iowa Code section 155A.32.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.23(124,155A) Individuals qualified to administer. 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. The board designates the following as qualified individuals to whom a prescriber may delegate the administration of prescription drugs.

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

This rule is intended to implement Iowa Code section 155A.44.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—8.24(155A) Documented verification. The pharmacist shall provide, document, and retain a record of 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. In an approved technician product verification program, the checking technician shall provide, document, and retain a record of the final verification for the accuracy of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18; **ARC 5007C**, IAB 3/25/20, effective 4/29/20]

657—8.25 Reserved.

657—8.26(155A) Continuous quality improvement program. Pursuant to rule 657—8.3(155A), each pharmacy licensed to provide pharmaceutical services to patients in Iowa shall implement or participate in a continuous quality improvement program (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 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.* Pursuant to rule 657—8.3(155A), each pharmacy shall have 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 quarterly, 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 but no more than three days following discovery of the event 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.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 2413C**, IAB 2/17/16, effective 3/23/16; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

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(135,147A) Opioid antagonist dispensing by pharmacists by standing order. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

657—8.32(124,155A) Individuals qualified to administer. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

657—8.33(155A) Vaccine administration by pharmacists. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

657—8.34(155A) Collaborative drug therapy management. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

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. The current pharmacy license certificate shall be displayed in a position visible to the public. The board may issue any of the following types of pharmacy licenses: a general pharmacy license, a hospital pharmacy license, a limited use pharmacy license, or a nonresident pharmacy license. Nonresident pharmacy license applicants shall comply with board rules regarding nonresident pharmacy practice except when a waiver has been granted. Applicants for general or hospital pharmacy practice shall comply with board rules regarding general or hospital pharmacy practice except when a waiver has been granted. Any pharmacy that dispenses controlled substances to Iowa residents must also register pursuant to 657—Chapter 10.

8.35(1) *Limited use pharmacy license.* A limited use pharmacy license may be issued for nuclear pharmacy practice, correctional facility pharmacy practice, veterinary pharmacy practice, telepharmacy practice, and other limited use practice settings. Applications for a limited use pharmacy license shall be considered on a case-by-case basis.

8.35(2) *Application.* Applicants for initial licensure, license renewal, license reactivation, or license changes pursuant to subrule 8.35(6) shall complete the relevant pharmacy license application and shall include all required information and attachments. All pharmacy license applications require submission of a nonrefundable $135 license fee plus applicable penalty fees. The application shall include the signature of the pharmacy owner's authorized representative and shall require at a minimum the following:

a. Disclosure of pharmacy ownership information, including information about the pharmacy's registered agent;

b. Identification and signature of the pharmacist in charge;

c. The identification of and average number of hours worked by all pharmacists, pharmacist-interns, pharmacy technicians, and pharmacy support persons working in the pharmacy;

d. Criminal and disciplinary history information;

e. Description of the scope of services provided by the pharmacy; and

f. If the pharmacy is located outside of Iowa, identification of a registered agent located in Iowa.

8.35(3) *License renewal.* A pharmacy license shall be renewed before January 1 of each year. An initial pharmacy license issued between November 1 and December 31 shall not require renewal until the following calendar year. The nonrefundable fee for a timely license renewal shall be $135.

a. Delinquent license grace period. A pharmacy license renewal application that is postmarked or hand-delivered to the board after January 1 but prior to February 1 following expiration shall be considered delinquent and shall require the nonrefundable payment of the renewal fee plus a penalty fee of $135. A pharmacy that submits a completed license renewal application, application fee, and penalty fee postmarked or delivered to the board office by January 31 shall not be subject to disciplinary action for continuing to operate in the month of January.

b. Delinquent license reactivation beyond grace period. If a pharmacy license is not renewed prior to the expiration of the one-month grace period identified in paragraph 8.35(3)*"a,"* the pharmacy may not operate or provide pharmacy services to patients in the state of Iowa until the license is reactivated. A pharmacy without a current license may apply for license reactivation by submitting an application for reactivation and a nonrefundable $540 reactivation fee. As part of the reactivation application, the pharmacy shall disclose the prescriptions dispensed and the services, if any, that were provided to Iowa patients while the license was delinquent. A pharmacy that continues to operate or provide pharmacy services in Iowa without a current license may be subject to disciplinary sanctions.

8.35(4) *Inspection of pharmacy location.*

a. A new pharmacy location in Iowa shall require an on-site inspection by an authorized agent of the board. Application for a pharmacy license and other required registrations shall be submitted to the board at least 14 days prior to the anticipated inspection. Any deficiencies identified during the inspection shall be corrected and verified by an authorized agent of the board prior to the issuance of the pharmacy license. Prescription drugs, including controlled substances, may not be delivered to a new pharmacy location prior to the delivery of the pharmacy license and registration certificates.

b. A pharmacy location in Iowa which is applying for a different license type than previously held may be subject to an inspection prior to the issuance of the new license.

8.35(5) *Failure to complete licensure.* An application for a pharmacy license, including any other required registration applications, will become null and void if the applicant fails to complete the licensure process within six months of acceptance 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 a satisfactory inspection by an agent of the board pursuant to this rule. When an applicant fails to timely complete the licensure process, fees submitted with applications will not be transferred or refunded. If the applicant intends to proceed with a pharmacy license, a new application and fee shall be required.

8.35(6) *Pharmacy license changes.* When a pharmacy changes its name, location, ownership, pharmacist in charge, or license type, a completed pharmacy license application with a nonrefundable $135 fee shall be submitted to the board pursuant to subrule 8.35(2). Upon receipt of the completed application and fee, the board shall issue an updated pharmacy license certificate, pending any necessary inspection pursuant to paragraph 8.35(4)*"b,"* unless the board identifies any ground for denial of the license. Any restrictions or disciplinary history associated with the previous pharmacy shall remain unchanged. A pharmacy wishing to disassociate itself from the previously licensed pharmacy restrictions or disciplinary history may petition the board for such disassociation. The burden is on the pharmacy to demonstrate that the current pharmacy is not associated with or responsible for the pharmacy as it previously existed. The old license certificate shall be returned to the board within ten days of receiving the updated license certificate.

a. Name. A change of the name under which the pharmacy is doing business shall require submission of a pharmacy license application and appropriate fee prior to the change of name.

b. Location. A change of pharmacy location shall require submission of a pharmacy license application and appropriate fee prior to the change of location. A pharmacy undergoing a change in location is required to notify patients of the change in accordance with paragraph 8.35(7)*"d."* A change of pharmacy location in Iowa may require an on-site inspection of the new location as provided in subrule 8.35(4).

c. Ownership. A change in ownership of a pharmacy shall require submission of a pharmacy license application and appropriate fee prior to the change in ownership. A change of ownership occurs when the owner listed on the pharmacy's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the pharmacy's most recent pharmacy application. A pharmacy undergoing a change in ownership is required to notify the pharmacist in charge and patients of the change in accordance with subrule 8.35(7). A change of ownership effectively consists of closing a pharmacy and opening a new pharmacy.

d. Pharmacist in charge. In addition to the requirements of this paragraph, a change of pharmacist in charge for a nonresident pharmacy shall require registration of the new permanent pharmacist in charge if the pharmacist in charge is not currently registered by the board or licensed to practice pharmacy in Iowa.

(1) If a permanent pharmacist in charge has been identified by the time of the vacancy, a pharmacy license application identifying the new pharmacist in charge, along with the appropriate fee, shall be submitted to the board within ten days of the change.

(2) If a permanent pharmacist in charge has not been identified by the time of the vacancy, a temporary pharmacist in charge shall be identified. Written notification identifying the temporary pharmacist in charge shall be submitted to the board within ten days of the vacancy.

(3) If a permanent pharmacist in charge was not identified within ten days of the vacancy, the pharmacy shall, within 90 days of the vacancy, identify a permanent pharmacist in charge. A pharmacy license application identifying the permanent pharmacist in charge, along with appropriate fee, shall be submitted to the board within ten days of the appointment of a permanent pharmacist in charge. The pharmacy license application and the pharmacist in charge registration application, if needed, including appropriate fees, shall be received by the board within 90 days of the original vacancy of the permanent pharmacist in charge position.

e. License type. A change in pharmacy license type shall require submission of a pharmacy license application and appropriate fee prior to the change in license type. A pharmacy changing license type shall notify the pharmacist in charge and patients of the change in accordance with subrule 8.35(7).

f. License change application submission. An application for license change shall be timely submitted pursuant to this subrule. A licensed pharmacy that has timely submitted an application for license change and fee may continue to service Iowa patients while the license change is pending final approval. An applicant who has submitted an application for license change after the required date of submission pursuant to this subrule but within 30 days of the required date of submission shall be assessed a nonrefundable late penalty fee of $135 in addition to the license fee. An applicant who has submitted an application for license change 31 days or later following the required date of submission pursuant to this subrule shall be assessed a nonrefundable late penalty fee of $540.

8.35(7) *Closing or sale of a pharmacy.* A closing pharmacy shall ensure that all pharmacy records are transferred to another licensed pharmacy that agrees to act as custodian of the records for at least two years. A pharmacy shall not execute a sale or closing of a pharmacy unless there exists an adequate period of time prior to the pharmacy's closing for delivery of the notifications to the pharmacist in charge, the board, the DEA, and pharmacy patients as required by this subrule. The executive director may exempt a pharmacy from one or more of the notification requirements in the event of an unforeseeable closure.

a. Pharmacist in charge notification. At least 40 days prior to the effective date of the sale or closing of a pharmacy, the pharmacist in charge of the closing pharmacy shall be notified of the proposed sale or closing. Information regarding the pending sale or closure of the pharmacy may be kept confidential until public notifications, which are required 30 days prior to the pharmacy's closing, are made. The pharmacist in charge of the closing pharmacy shall provide input and direction to the

pharmacy owner regarding the responsibilities of the closing pharmacy, including the notifications, deadlines, and timelines established by this subrule. The pharmacist in charge of the purchasing or receiving pharmacy shall be notified of the pending transaction at least 30 days prior to the sale or closure of the pharmacy.

b. Board and DEA notifications. At least 30 days prior to the closing of a pharmacy, a written notice shall be sent to the board. Notification to the DEA shall be pursuant to federal regulation. Notification to the board shall include:

(1) The anticipated date of closing or transfer of prescription drugs or records.

(2) 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.

(3) The name, address, DEA registration number, Iowa pharmacy license number, and CSA registration number of the location at which records will be maintained.

c. Terms of sale or purchase. If the closing is due to the sale of the pharmacy, a copy of the sale or purchase agreement, not including information regarding the monetary terms of the transaction, shall be submitted to the board upon the request of the board. The agreement shall include a written assurance from the closing pharmacy to the purchasing pharmacy that the closing pharmacy has given or will be giving notice to its patients as required by this subrule.

d. Patient notification. At least 30 days prior to closing, a closing pharmacy shall make a reasonable effort to notify all patients who had a prescription filled by the closing pharmacy within the last 18 months that the pharmacy intends to close, including the anticipated closing date.

(1) Written notification shall identify the pharmacy that will be receiving the patient's records. The notification shall advise patients that all patient records will be transferred to the identified pharmacy and that patients may contact the closing pharmacy to request the transfer of remaining refills to a pharmacy of the patient's choice. The notification shall also advise patients that after the date of closing, patients may contact the pharmacy to which the records have been transferred.

(2) Written notification shall be delivered to each patient at the patient's last address on file with the closing pharmacy by direct mail or personal delivery. A pharmacy shall not be required to provide written notice to more than one patient within the same household.

(3) Public notice shall be provided in a location and manner clearly visible to patients in the pharmacy pickup locations including drive-through prescription pickup lanes, on pharmacy or retail store entry and exit doors, and at pharmacy prescription counters.

e. Patient communication by receiving pharmacy. A pharmacy receiving the patient records of another pharmacy shall not contact the patients of the closing pharmacy until after the transfer of those patient records from the closing pharmacy to the receiving pharmacy and after the closure of the closing pharmacy.

f. Prescription drug inventory. A complete inventory of all prescription drugs being transferred shall be taken as of the close of business. The inventory shall serve as the ending inventory for the closing pharmacy as well as a record of additional or starting inventory for the pharmacy to which the drugs are transferred. A copy of the inventory shall be maintained in the records of the purchasing pharmacy for at least two years.

(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 rule 657—10.19(124).

(3) The inventory of all noncontrolled prescription drugs shall include the name, strength, dosage form, and quantity, which may be estimated.

(4) Controlled substances and prescription drugs 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 drugs.

g. Return of certificates and forms. The pharmacy license certificate and CSA registration certificate of the closing or selling pharmacy shall be returned to the board within ten days of closing

or sale. The pharmacy shall be responsible for complying with federal DEA regulations for the cancellation and return of DEA forms and certificates.

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

8.35(8) *Reporting discipline and criminal convictions.* A pharmacy shall, no later than 30 days after the final action, provide written notice to the board of any discipline imposed by any licensing authority on any license or registration held by the pharmacy. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, or voluntary surrender. A pharmacy shall, no later than 30 days after a conviction, provide written notice to the board of any criminal conviction of the pharmacy or of any pharmacy owner when that conviction is related to prescription drugs or to the operation of the pharmacy. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

8.35(9) *License verification fee.* The board may require a nonrefundable fee of $15 for completion of a request for written license verification of any pharmacy license.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 9526B**, IAB 6/1/11, effective 7/6/11 (See Delay note at end of chapter); **ARC 9693B**, IAB 9/7/11, effective 8/11/11; **ARC 0504C**, IAB 12/12/12, effective 1/16/13; **ARC 1962C**, IAB 4/15/15, effective 5/20/15; **ARC 3236C**, IAB 8/2/17, effective 9/6/17; **ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 3858C**, IAB 6/20/18, effective 7/25/18; **ARC 4268C**, IAB 1/30/19, effective 3/6/19; **ARC 5007C**, IAB 3/25/20, effective 4/29/20]

657—8.36 to **8.39** Reserved.

657—8.40(155A,84GA,ch63) Pharmacy pilot or demonstration research projects. Rescinded **ARC 3858C**, IAB 6/20/18, effective 7/25/18.

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.31 through 155A.35, and 155A.41.

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CHAPTER 9
AUTOMATED MEDICATION DISTRIBUTION SYSTEMS AND TELEPHARMACY SERVICES

Rescinded **ARC 3640C**, IAB 2/14/18, effective 3/21/18

CHAPTER 10
CONTROLLED SUBSTANCES

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

657—10.1(124) Purpose and scope. This chapter establishes the minimum standards for any activity that involves controlled substances. Any person or business that manufactures; distributes; dispenses; prescribes; conducts instructional activities, research, or chemical analysis with; or imports or exports controlled substances listed in Schedules I through V of Iowa Code chapter 124 in or into the state of Iowa, or that proposes to engage in such activities, shall obtain and maintain a registration issued by the board unless exempt from registration pursuant to rule 657—10.8(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. A registration is not transferable to any person or business.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.2(124) Definitions. For the purposes of this chapter, the following definitions shall apply:

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

"Board" means the Iowa board of pharmacy.

"CSA" means the Iowa uniform controlled substances Act.

"CSA registration" or *"registration"* means the registration issued by the board pursuant to the CSA that signifies the registrant's authorization to engage in registered activities with controlled substances.

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

"Individual practitioner" means a physician or surgeon (M.D.), osteopathic physician or surgeon (D.O.), dentist (D.D.S. or D.M.D.), doctor of veterinary medicine (D.V.M.), podiatric physician (D.P.M.), optometrist (O.D.), physician assistant (P.A.), resident physician, advanced registered nurse practitioner (A.R.N.P.), or prescribing psychologist.

"Prescription monitoring program," "PMP," or *"program"* means the program established pursuant to 657—Chapter 37 for the collection and maintenance of PMP information and for the provision of PMP information to authorized individuals.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4455C**, IAB 5/22/19, effective 6/26/19]

657—10.3(124) Who shall register. The following persons or businesses shall register on forms provided by the board:

1. Manufacturers, distributors, importers, and exporters located in Iowa. Effective January 1, 2018, nonresident manufacturers, distributors, importers, and exporters distributing controlled substances into Iowa.
2. Reverse distributors located in Iowa. Effective January 1, 2018, nonresident reverse distributors engaging in the transfer of controlled substances with registrants located in Iowa.
3. Individual practitioners located in Iowa who are administering, dispensing, or prescribing controlled substances and individual practitioners located outside of Iowa who are dispensing or prescribing controlled substances via telehealth services to patients located in Iowa.
4. Pharmacies located in Iowa that are dispensing controlled substances. Effective January 1, 2018, pharmacies located outside of Iowa that are delivering controlled substances to patients located in Iowa.
5. Hospitals located in Iowa that are administering or dispensing controlled substances. Effective January 1, 2018, hospitals located outside of Iowa that are administering or dispensing controlled substances to patients located in Iowa.
6. Emergency medical service programs that are administering controlled substances to patients located in Iowa.
7. Care facilities that are located in Iowa.

8. Researchers, analytical laboratories, and teaching institutions that are located in Iowa.
9. Animal shelters and dog training facilities that are located in Iowa.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.4 Reserved.

657—10.5(124) Application. Applicants for initial registration, registration renewal pursuant to rule 657—10.6(124), or modifications pursuant to rule 657—10.9(124) shall complete the appropriate application and shall include all required information and attachments.

10.5(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. If the applicant is a pharmacy, the responsible individual shall be the pharmacist in charge, unless the applicant petitions the board for an alternate responsible individual.

10.5(2) *Prescribing practitioner PMP registration required.* A prescribing practitioner, except for a licensed veterinarian, shall register for the PMP at the same time the prescribing practitioner applies for registration.

10.5(3) *Registration fee exemptions.* 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. 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 (analytical laboratory). Such laboratories shall be exempt from any registration fee. Exemption from payment of any fees as provided in this subrule does not relieve the entity of registration or of any other requirements or duties prescribed by law.

10.5(4) *Fees.* Each application shall include a nonrefundable registration fee, except as provided in subrule 10.5(3), of $90 per biennium, which may be prorated to the expiration date of the applicant's underlying professional license or other board license if applicable, and may include a nonrefundable surcharge of not more than 25 percent of the registration fee for deposit into the program fund.

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657—10.6(124) Registration renewal. Each registration shall be renewed prior to its expiration. A registrant may renew its registration up to 60 days prior to the registration expiration. The nonrefundable fee for registration renewal shall be $90 per biennium and may include a nonrefundable surcharge of not more than 25 percent of the registration fee for deposit into the program fund.

10.6(1) *Delinquent registration grace period.* A registration renewal application that is submitted after expiration but within 30 days following expiration shall be considered delinquent and shall require the nonrefundable payment of the application fee plus a nonrefundable late penalty fee of $90 and may require payment of a surcharge of not more than 25 percent of the applicable fees for deposit into the program fund. A registrant that submits a completed registration renewal application, nonrefundable late application fee, and nonrefundable late penalty fee within 30 days following expiration shall not be subject to disciplinary action for continuing to operate in the 30 days following expiration.

10.6(2) *Delinquent registration reactivation beyond grace period.* If a registration renewal application is not postmarked or hand-delivered to the board office within 30 days following the registration's expiration date, the registrant may not conduct operations that involve controlled substances until the registrant reactivates the registration. A registrant may apply for reactivation by submitting a registration application for reactivation. The nonrefundable fee for reactivation shall be $360 and may include a nonrefundable surcharge of not more than 25 percent of the applicable fee for deposit into the program fund. As part of the reactivation application, the registrant shall disclose

the activities conducted with respect to controlled substances while the registration was expired. A registrant that continues to conduct activities with respect to controlled substances without an active registration may be subject to disciplinary sanctions.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4455C**, IAB 5/22/19, effective 6/26/19]

657—10.7(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.

10.7(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.

10.7(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.

10.7(3) *Dispensing, administering, prescribing, or instructing with controlled substances.* These independent activities include, but are not limited to, prescribing, administering, and dispensing 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 these independent activities may conduct research and instructional activities with those substances for which the person or business is registered to the extent authorized under state law. If an entity that engages in the distribution, administration, dispensing, or storing of controlled substances maintains multiple licenses, such as a hospital that has both inpatient and outpatient pharmacies, a separate registration shall be maintained for each license.

10.7(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 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.

10.7(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 section 124.302(3), and may conduct instructional activities with controlled substances.

10.7(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 section 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.

10.7(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.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.8(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, dispensed, stored, or collected for the purpose of disposal unless the person or business is exempt from registration pursuant to Iowa Code section 124.302(3), this rule, or federal regulations.

10.8(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 section 124.302(3).

10.8(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.

10.8(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.

10.8(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 at the location of the hospital.

10.8(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 practitioner 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 or practice in the hospital, institution, internship program, or residency program.

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).

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.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.9(124) Modification or termination of registration. A registered individual or business shall apply to modify a current registration as provided by this rule. When submission of an application and fee is required, such application and fee shall be timely submitted pursuant to rule 657—10.5(124). A registrant which has timely submitted an application for registration modification and fee may continue to service Iowa patients while the registration modification is pending final approval. A registrant which

has submitted an application for registration modification after the required date of submission pursuant to this rule but within 30 days of the required date of submission shall be assessed a nonrefundable late penalty fee of $90 in addition to the application fee. A registrant which has submitted an application for registration modification 31 days or later following the required date of submission pursuant to this rule shall be assessed a nonrefundable late penalty fee of $360.

10.9(1) *Change of substances authorized.* Any registrant shall 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.

10.9(2) *Change of address of registered location.*

a. Individual practitioner or researcher. An entity registered as an individual practitioner or researcher shall 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, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter. An entity registered as a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall apply to change the address of the registered location by submitting a completed application and fee for registration as provided in rule 657—10.5(124). The registrant shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board's rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration no less than 30 days in advance of the change of address.

10.9(3) *Change of registrant's name.*

a. Individual practitioner or researcher. An entity registered as an individual practitioner or researcher shall apply to change the registrant's name by submitting a written request to the board. The request shall include the registrant's current name, 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, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter. An entity registered as a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall apply to change the registrant name by submitting a completed application and fee for registration as provided in rule 657—10.5(124). The registrant shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board's rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration no less than 30 days in advance of the change of registrant's name.

10.9(4) *Change of ownership of registered business entity.* A change of immediate ownership of a pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter shall require the submission of a completed application and fee for registration as provided in rule 657—10.5(124). The registrant shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board's rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration no less than 30 days in advance of the change of registrant's ownership.

10.9(5) *Change of responsible individual.* Any registrant, except an individual practitioner or researcher or a pharmacy or hospital, shall 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, and 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 or transferred.

b. Pharmacy, hospital, care facility, service program, manufacturer, distributor, analytical laboratory, teaching institution, importer, or exporter. The registrant shall submit a completed application and fee for change in registration simultaneously with any other required application pursuant to the board's rules for the applicable license or registration. In the absence of a simultaneous license or registration application, the registrant shall submit a completed application and fee for change in registration within ten days of the identification of a new responsible individual.

10.9(6) *Termination of registration.* 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. A registration issued to an individual shall terminate upon the death of the individual.

10.9(7) *Cancellation of registration.* An individual registrant who no longer needs a registration due to discontinuation of practice in Iowa or discontinuation of possessing, administering, dispensing, or prescribing controlled substances shall contact the board to request cancellation of the registration. An individual registrant may renew the registration upon a return to practice in Iowa or a return to possessing, administering, dispensing, or prescribing controlled substances by submitting an application and a nonrefundable fee for registration renewal of $90 per biennium and a nonrefundable surcharge of not more than 25 percent of the registration fee for deposit into the program fund.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4455C**, IAB 5/22/19, effective 6/26/19; **ARC 5096C**, IAB 7/15/20, effective 8/19/20]

657—10.10(124) Denial of application or discipline of registration.

10.10(1) *Grounds for denial or discipline.* The board may deny any application or discipline any registration upon a finding that the applicant or registrant:

a. Has furnished false or fraudulent material information.

b. Has had the applicant's or registrant's federal registration to manufacture, distribute, or dispense controlled substances suspended, revoked, or otherwise sanctioned.

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 if entry of the judgment or sentence has been withheld and the applicant or registrant has been placed on probation.

d. Has committed such acts as would render the applicant's or registrant's registration under Iowa Code section 124.303 inconsistent with the public interest as determined by that section.

e. Has been subject to discipline by the applicant's or registrant's respective professional licensing board and the discipline revokes or suspends the applicant's or registrant's professional license or otherwise disciplines the applicant's or registrant's professional license in a way that restricts the applicant's or registrant's authority to handle or prescribe controlled substances. A copy of the record of licensee discipline or a copy of the licensee's surrender of the professional license shall be conclusive evidence.

f. Has failed to obtain or maintain active registration while engaged in activities which require registration.

10.10(2) *Considerations in denial of application or discipline of registration.* In determining the public interest, the board shall consider all the following factors:

a. Maintenance of effective controls against diversion of controlled substances into channels other than legitimate medical, scientific, or industrial channels.

b. Compliance with applicable state and local law.

c. Any convictions of the applicant or registrant 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 or registrant'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 or registrant'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.

h. Failure of a prescribing practitioner, except a licensed veterinarian, to register with the PMP pursuant to subrule 10.5(2).

10.10(3) *Proceedings.*

a. Prior to denying an application for registration, the board shall serve upon the applicant a notice of intent to deny the application. An applicant has 30 days to appeal a notice of intent to deny the application. If the notice of intent to deny the application is timely appealed, a notice of hearing shall be issued, initiating a contested case proceeding governed by 657—Chapter 35. Proceedings to refuse renewal of a registration shall not abate the existing registration, which shall remain in effect pending the outcome of the contested case proceeding. A registration may be disciplined in accordance with 657—Chapters 35 and 36.

b. Prior to sanctioning a registration, the board shall serve upon the registrant a notice of hearing and statement of charges. The notice shall contain a statement of the basis therefore and shall call upon the 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 notice. The notice shall also contain a statement of the legal basis for such hearing and for the sanction of registration and a summary of the matters of fact and law asserted. 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. A registration may be disciplined in accordance with 657—Chapters 35 and 36.

10.10(4) *Disposition of controlled substances.* Upon service of an order of the board suspending or revoking a 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 filing 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.

[**ARC 4455C**, IAB 5/22/19, effective 6/26/19]

657—10.11(124,147,155A) Registration verification. The board may require a nonrefundable fee of $15 for completion of a request for written verification of any registration.

[**ARC 4455C**, IAB 5/22/19, effective 6/26/19]

657—10.12(124) 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.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.13(124) Security requirements. All registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant 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.

10.13(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 or safe.

b. Controlled substances listed in Schedules II through V may be stored in a securely locked, substantially constructed cabinet or safe. 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.

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

10.13(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 electronic 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.

m. The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances.

10.13(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.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.14(124) Accountability of controlled substances. The registrant shall maintain ultimate accountability of controlled substances and records maintained at the registered location.

10.14(1) *Records.* Pursuant to rule 657—10.36(124,155A), records shall be available for inspection and copying by the board or its authorized agents for two years from the date of the record.

10.14(2) *Policies and procedures.* The registrant shall have policies and procedures that identify, at a minimum:

a. Adequate storage for all controlled substances to ensure security and proper conditions with respect to temperature and humidity.

b. Access to controlled substances and records of controlled substances by employees of the registrant.

c. Proper disposition of controlled substances.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.15 Reserved.

657—10.16(124) Receipt and disbursement of controlled substances. Each transfer of a controlled substance between two registrants, to include a transfer between two separately registered locations regardless of any common ownership, except as provided in subrule 10.16(2), shall require a record of the transaction. Each registrant shall maintain a copy of the record for at least two years from the date of the transfer. Records of the transfer of Schedule II controlled substances shall be created and maintained separately from records of the transfer of Schedules III through V controlled substances pursuant to rule 657—10.36(124,155A). Upon receipt of a controlled substance, the individual responsible for receiving the controlled substance shall date and sign the receipt record.

10.16(1) *Record.* The record, 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 which 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 which the substances were distributed.

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 which the substances were distributed for disposal, if appropriate.

10.16(2) *Distribution of samples and other complimentary packages.* 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 provides to the practitioner a record that contains the information found in this subrule. The individual responsible for receiving the controlled substances shall sign and date the record.

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, dosage form, and quantity of the specific controlled substances delivered.

d. The date of delivery.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.17(124) Ordering or distributing Schedule I or II controlled substances. A registrant authorized to order or distribute Schedule I or II controlled substances shall do so only pursuant to and in compliance with DEA regulations via a DEA Form 222 or via the DEA Controlled Substances Ordering System (CSOS).

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 5349C**, IAB 12/30/20, effective 2/3/21]

657—10.18(124) Schedule II perpetual inventory. Each registrant located in Iowa that maintains Schedule II controlled substances shall maintain a perpetual inventory system for all Schedule II controlled substances pursuant to this rule. All records relating to the perpetual inventory shall be maintained at the registered location 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. The perpetual inventory shall accurately reflect the on-hand inventory of Schedule II substances, and the registrant is responsible for

ensuring that the perpetual inventory record is accurate and matches the actual on-hand inventory at all times.

10.18(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.

10.18(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 receipt, disbursement, and current balance of each individual drug or NDC number. The record shall also include incident reports and reconciliation records pursuant to subrules 10.18(3) and 10.18(4).

10.18(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.

10.18(4) *Reconciliation.* The registrant shall be responsible for reconciling or ensuring the completion of a reconciliation of the perpetual inventory balance with the physical inventory of all Schedule II controlled substances at least annually. In case of any discrepancies between the physical inventory and the perpetual inventory, the registrant shall be notified immediately. The registrant shall determine the need for further investigation, and significant discrepancies shall be reported to the board pursuant to rule 657—10.21(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 its authorized agents 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 individual responsible for a disbursement verifies that the physical inventory matches the perpetual inventory following each disbursement 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. If any Schedule II controlled substances in the registrant's current inventory have been disbursed and verified in this manner within the year and there are no discrepancies noted, no additional reconciliation action is required. A perpetual inventory record for a drug that has had no activity within the year shall be reconciled pursuant to paragraph 10.18(4)*"b."*

b. A physical count of each Schedule II controlled substance stocked by the registrant 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.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 5349C**, IAB 12/30/20, effective 2/3/21]

657—10.19(124) Physical count and record of inventory. Each registrant shall be responsible for taking a complete and accurate inventory of all stocks of controlled substances under the control of the registrant pursuant to this rule. The responsible individual may delegate the actual taking of any inventory.

10.19(1) *Record and procedure.* Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.18(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. Controlled substances on hand shall include prescriptions prepared for dispensing to a patient but not yet delivered to the patient, substances maintained in emergency medical service programs, care facility or hospice emergency supplies, outdated or adulterated substances pending destruction, and substances stored in a warehouse on behalf of the registrant. Controlled substances obtained through an authorized collection program for the purpose of disposal shall not be examined, inspected, counted, sorted, inventoried, or otherwise handled.

d. 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.

(3) The quantity of the substance.

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

(5) The signature of the person or persons responsible for taking the inventory.

(6) The date and time (opening or closing) of the inventory.

g. For all substances listed in Schedule I or II, the quantity shall be an exact count or measure of the substance.

h. For all substances listed in Schedule III, IV, or V, 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. Products packaged in nonincremented containers may be estimated to the nearest one-fourth container.

10.19(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, storage, 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.

10.19(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 372 days after the date of the previous annual inventory.

10.19(4) *Change of ownership, pharmacist in charge, or registered location.* When there is a change in ownership, pharmacist in charge, or location for a registration, an inventory shall be taken of all controlled substances in compliance with subrule 10.19(1). The inventory shall be taken following the close of business the last day under terminating ownership, terminating pharmacist in charge's employment, or at the location being vacated. The inventory shall serve as the ending inventory for the terminating owner, terminating pharmacist in charge, or location being vacated, as well as a record of the beginning inventory for the new owner, pharmacist in charge, or location.

10.19(5) *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 which the substances are transferred.

10.19(6) *New or rescheduled controlled substances.* On the effective date of the addition of a previously noncontrolled substance to any schedule of controlled substances or the rescheduling of a previously controlled substance to another schedule, any registrant who possesses the newly scheduled or rescheduled controlled substance shall take an inventory of all stocks of the substance on hand. That inventory record shall be maintained with the most recent controlled substances inventory record. Thereafter, the controlled substance shall be included in the appropriate schedule of each inventory made by the registrant.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.20 Reserved.

657—10.21(124) Report of theft or loss. A registrant shall report to the board and the DEA any theft or significant loss of controlled substances when the loss is attributable to other than inadvertent error. Thefts or other losses of controlled substances shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them.

10.21(1) *Immediate notice to board.* If the theft was committed by a registrant or licensee of the board, or if there is reason to believe that the theft was committed by a registrant or licensee of the board, the registrant from which the controlled substances were stolen shall notify the board immediately upon discovery of the theft and shall identify to the board the registrant or licensee suspected of the theft.

10.21(2) *Immediate notice to DEA.* A registrant shall deliver notice, immediately upon discovery of a reportable theft or loss of controlled substances, to the Des Moines DEA field office via telephone, facsimile, or a brief written message explaining the circumstances of the theft or loss.

10.21(3) *Timely report submission.* Within 14 calendar days of discovery of the theft or loss, a registrant shall submit directly to the DEA a Form 106 or alternate required form via the DEA website at www.deadiversion.usdoj.gov/. A copy of the report that was completed and submitted to the DEA shall be immediately submitted to the board via facsimile, email attachment, or personal or commercial delivery.

10.21(4) *Record maintained.* A copy of the report shall be maintained in the registrant's files for a minimum of two years following the date the report was completed.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.22(124) Disposal of registrant stock. A registrant shall dispose of controlled substances pursuant to the requirements of this rule. Disposal records shall be maintained by the registrant for at least two years from the date of the record.

10.22(1) *Registrant stock supply.* Controlled substances shall be removed from current inventory and disposed of by one of the following procedures.

a. The registrant shall utilize the services of a DEA-registered and Iowa-licensed reverse distributor.

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.

(3) By such other means as the board may determine to ensure that drugs do not become available to unauthorized persons.

10.22(2) *Waste resulting from administration or compounding.* 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, a certified paramedic, 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 wastage. The record shall include the following:

a. The controlled substance wasted.

b. The date of wastage.

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.

e. The reason for the waste.

f. The signatures of both individuals involved in the wastage.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4455C**, IAB 5/22/19, effective 6/26/19]

657—10.23(124) Disposal of previously dispensed controlled substances.

10.23(1) *Registrant disposal.* Except as provided in 657—Chapter 23 for care facilities, a registrant may not dispose of previously dispensed controlled substances unless the registrant has modified its registration with DEA to administer an authorized collection program. A registrant shall not take possession of a previously dispensed controlled substance except for reuse for the same patient or except as provided in paragraph 10.23(2)*"b."*

10.23(2) *Hospice disposal.*

a. An employee of a hospice program, acting within the scope of employment, may dispose of a controlled substance of a hospice program patient following the death of the patient or the expiration of the controlled substance pursuant to and in compliance with federal law.

b. A physician of a hospice program patient may dispose of a patient's controlled substance which is no longer required due to a change in the patient's care plan.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4455C**, IAB 5/22/19, effective 6/26/19]

657—10.24(124,126,155A) Prescription requirements. All prescriptions for controlled substances shall be dated as of, and signed on, the day issued. Controlled substances prescriptions shall be valid for six months following date of issue. A prescription for a Schedule III, IV, or V controlled substance may include authorization to refill the prescription no more than five times within the six months following date of issue. A prescription for a Schedule II controlled substance shall not be refilled. Beginning January 1, 2020, all prescriptions for controlled substances shall be transmitted electronically to a pharmacy pursuant to rule 657—21.6(124,155A), except as provided in rule 657—21.8(124,155A).

10.24(1) *Form of prescription.* All prescriptions for controlled substances 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 for controlled substances issued by individual prescribers shall include the legibly preprinted, typed, or hand-printed name of the prescriber as well as the prescriber's written or electronic signature. A prescription for a controlled substance issued prior to January 1, 2020, or a prescription for a controlled substance that is exempt from the electronic prescription mandate pursuant to rule 657—21.8(124,155A), may be transmitted via nonelectronic methods as described in this rule.

a. When an oral order is not permitted, or when a prescriber is unable to prepare and transmit an electronic prescription in compliance with DEA requirements for electronic prescriptions, prescriptions shall be written with ink, indelible pencil, or typed print and shall be manually signed by the prescriber. If the prescriber utilizes an electronic prescription application that meets DEA requirements for electronic prescriptions, the prescriber may electronically prepare and transmit a prescription for a controlled substance to a pharmacy that utilizes a pharmacy prescription application that meets DEA requirements for electronic prescriptions.

b. A prescriber's agent may prepare a prescription for the review, authorization, and manual or electronic signature of the prescriber, but the prescribing practitioner is responsible for the accuracy, completeness, and validity of the prescription.

c. An electronic prescription for a controlled substance shall not be transmitted to a pharmacy except by the prescriber in compliance with DEA regulations.

d. A prescriber shall securely maintain the unique authentication credentials issued to the prescriber for utilization of the electronic prescription application and authentication of the prescriber's

electronic signature. Unique authentication credentials issued to any individual shall not be shared with or disclosed to any other prescriber, agent, or individual.

e. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this rule.

10.24(2) *Verification by pharmacist.*

a. The pharmacist shall verify the authenticity of the prescription with the individual prescriber or the prescriber's agent in each case when a written or oral 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 shall verify the authenticity of the prescription with the individual prescriber or the prescriber's agent in any case when the pharmacist questions the validity of, including the legitimate medical purpose for, the prescription. The pharmacist is required to record the manner by which the prescription was verified and include the pharmacist's name or unique identifier.

b. A pharmacist who receives a written, oral, or facsimile prescription shall not be required to verify that the prescription is subject to an exception to the electronic prescription mandate provided in rule 657—21.8(124,155A) and may dispense a prescription drug pursuant to an otherwise valid written, oral, or facsimile prescription pursuant to this rule.

10.24(3) *Intern, resident, foreign physician.* An intern, resident, or foreign physician exempt from registration pursuant to subrule 10.8(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 legibly printed name of the prescribing intern, resident, or foreign physician as well as the prescriber's signature.

10.24(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.

10.24(5) *Facsimile transmission of a controlled substance prescription.* With the exception of an authorization for emergency dispensing as provided in rule 657—10.26(124), a prescription for a controlled substance in Schedules II, III, IV and V may be transmitted via facsimile from a prescriber to a pharmacy only as provided in rule 657—21.7(124,155A).

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4580C**, IAB 7/31/19, effective 9/4/19]

657—10.25(124) Dispensing records. Each registrant shall create a record of controlled substances dispensed to a patient or research subject.

10.25(1) *Record maintained and available.* The record shall be maintained for two years from the date of dispensing and be available for inspection and copying by the board or its authorized agents.

10.25(2) *Record contents.* The record shall include the following information:

a. The name and address of the person to whom dispensed.

b. The date of dispensing.

c. The name or NDC number, strength, dosage form, and quantity of the substance dispensed.

d. The name of the prescriber, unless dispensed by the prescriber.

e. The unique identification of each technician, pharmacist, pharmacist-intern, prescriber, or prescriber's agent involved in dispensing.

f. The serial number or unique identification number of the prescription.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.26(124) Schedule II emergency prescriptions.

10.26(1) *Emergency situation defined.* For the purposes of authorizing an oral or facsimile transmission of a 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 manually signed written prescription to be presented to the pharmacy before the pharmacy dispenses the controlled substance, or the prescribing practitioner is unable to provide a DEA-compliant electronic prescription to the pharmacy before the pharmacy dispenses the controlled substance.

10.26(2) *Requirements of emergency prescription.* In the case of an emergency situation as defined in subrule 10.26(1), a pharmacist may dispense a controlled substance listed in Schedule II pursuant to a facsimile 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 or a DEA-compliant electronic prescription.

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 facsimile transmission or a written record of the oral transmission authorizing the emergency dispensing. A written record is not required to consist of a handwritten record and may be a printed facsimile or a print of a computer-generated record of the prescription if the printed record includes all of the required elements for the prescription. If the emergency prescription is transmitted by the practitioner's agent, the record shall include the first and last names and title of the individual who transmitted the prescription.

d. If the emergency prescription is transmitted via facsimile 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 facsimile 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 rule 657—10.24(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 10.26(2)*"c."*

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

g. Pursuant to federal law and subrule 10.27(3), the pharmacist may fill a partial quantity of an emergency prescription so long as the total quantity dispensed in all partial fillings does not exceed

the total quantity prescribed and that the remaining portions are filled no later than 72 hours after the prescription is issued.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.27(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 and federal regulations.

10.27(1) *Insufficient supply on hand.* If the pharmacist is unable to supply the full quantity authorized 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.

10.27(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 an LTCF or for 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 an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system pursuant to rule 657—21.5(124,155A).

10.27(3) *Patient or prescriber request.* At the request of the patient or prescriber, a prescription for a Schedule II controlled substance may be partially filled pursuant to this subrule and federal law. The total quantity dispensed in all partial fillings shall not exceed the total quantity prescribed. Except as provided in paragraph 10.26(2)*"g,"* the remaining portion of a prescription partially filled pursuant to this subrule may be filled within 30 days of the date the prescription was issued.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4455C**, IAB 5/22/19, effective 6/26/19]

657—10.28(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—23.9(124,155A), as applicable.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—10.29(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.

10.29(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.

10.29(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.

10.29(3) *Dates and instructions.* Each prescription issued pursuant to this rule shall be dated as of and manually or electronically 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.

10.29(4) *Authorized fill date unalterable.* Regardless of the provisions of rule 657—10.30(124), 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.

10.29(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.

10.29(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 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 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4580C**, IAB 7/31/19, effective 9/4/19]

657—10.30(124) Schedule II—changes to a prescription. 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.

10.30(1) *Changes prohibited.* 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.

10.30(2) *Changes authorized.* After consultation with the prescriber or the prescriber's agent 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.
e. The date the prescription was issued.
f. The prescriber's address or DEA registration number.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 5346C**, IAB 12/30/20, effective 2/3/21]

657—10.31 Reserved.

657—10.32(124) Schedule III, IV, or V prescription. 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. Beginning January 1, 2020, all prescriptions for controlled substances shall be transmitted electronically to a pharmacy pursuant to rule 657—21.6(124,155A), except as provided in rule 657—21.8(124,155A).

10.32(1) *Record.* Each filling and refilling of a prescription shall be entered in a uniformly maintained and readily retrievable record in accordance with rule 657—10.25(124). 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.

10.32(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 an authorized individual at the pharmacy 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, pharmacist-intern, or technician who obtains the oral authorization from the prescriber who issued the original prescription documents, on or with the original prescription, the date authorized, the quantity of each refill, the number of additional refills authorized, and the unique identification of the authorized individual.

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.

10.32(3) *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 pursuant to subrule 10.32(1). The total quantity dispensed in all partial fills shall not exceed the total quantity prescribed.

10.32(4) *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.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4580C**, IAB 7/31/19, effective 9/4/19]

657—10.33(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.

10.33(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.

10.33(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.

10.33(3) *Age of purchaser.* The purchaser shall be at least 18 years of age.

10.33(4) *Identification.* The pharmacist shall require every purchaser under this rule who is not known by the pharmacist to present a government-issued photo identification, including proof of age when appropriate.

10.33(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.

10.33(6) *Prescription not required under other laws.* No other federal or state law or regulation requires a prescription prior to distributing or dispensing the Schedule V controlled substance.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.34(124) Dispensing products containing ephedrine, pseudoephedrine, or phenylpropanolamine without a prescription. 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 an authorized dispenser pursuant to 657—Chapter 100 to a purchaser at retail pursuant to the conditions of this rule.

10.34(1) *Who may dispense.* Dispensing shall be by an authorized dispenser pursuant to 657—Chapter 100. This subrule does not prohibit, after the dispenser 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 another pharmacy employee.

10.34(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.

10.34(3) *Frequency and quantity.* Dispensing without a prescription 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 without a prescription to the same purchaser within a single calendar day shall not exceed 3,600 mg.

10.34(4) *Age of purchaser.* The purchaser shall be at least 18 years of age.

10.34(5) *Identification.* The dispenser shall require every purchaser under this rule to present a current government-issued photo identification, including proof of age when appropriate. The dispenser 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.

10.34(6) *Record.* Purchase records shall be recorded in the real-time electronic pseudoephedrine tracking system (PTS) established and administered by the governor's office of drug control policy pursuant to 657—Chapter 100. If the PTS is unavailable for use, the purchase record shall be recorded in an alternate format and submitted to the PTS as provided in 657—subrule 100.3(4).

a. *Alternate record contents.* The alternate 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 dispenser who approved the dispensing of the product.

b. *Alternate record format.* The record shall be maintained using one of the following options:

(1) A hard-copy record.

(2) A record in the pharmacy's electronic prescription dispensing record-keeping system that is capable of producing a hard-copy printout of a record.

(3) A record in an electronic data collection system that captures each of the data elements required by this subrule and that is capable of producing a hard-copy printout of a record.

c. *PTS records retrieval.* Pursuant to 657—subrule 100.4(6), the pharmacy shall be able to produce a hard-copy printout of transactions recorded in the PTS by the pharmacy for one or more specific products for a specified period of time upon request by the board or its representative or to such other persons or governmental agencies authorized by law to receive such information.

10.34(7) *Notice required.* The pharmacy shall ensure that the following notice is provided to purchasers of ephedrine, pseudoephedrine, or phenylpropanolamine products and that the notice is displayed with or on the electronic signature device or is displayed in the dispensing area and 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."
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4701C**, IAB 10/9/19, effective 11/13/19]

657—10.35 Reserved.

657—10.36(124,155A) Records. Every 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 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. Original records more than 12 months old may be maintained in a secure remote storage area unless such remote storage is prohibited under federal law. If the secure storage area is not located within the same physical structure as the registrant, the records must be retrievable within 48 hours of a request by the board or its authorized agent.

10.36(1) *Schedule I and II records.* Records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the registrant.

10.36(2) *Schedule III, IV, and V records.* 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.

10.36(3) *Date of record.* The date on which a controlled substance is actually received, imported, distributed, exported, disposed of, or otherwise transferred shall be used as the date of receipt, importation, distribution, exportation, disposal, or transfer.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.37 Reserved.

657—10.38(124) Revision of controlled substances schedules.

10.38(1) *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(4).

10.38(2) *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(4).

10.38(3) *Cannabis-derived products.* If a cannabis-derived product or investigational product approved as a prescription drug medication by the United States Food and Drug Administration is added to, eliminated from or revised in the federal schedule of controlled substances by the DEA and notice of the addition, elimination or revision is given to the board, the board shall similarly add, eliminate or revise the prescription drug medication in the schedule of controlled substances. Such action by the board shall be immediately effective upon the date of publication of the final regulation containing the addition, elimination or revision in the Federal Register.
[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 3743C**, IAB 4/11/18, effective 5/16/18; **ARC 5346C**, IAB 12/30/20, effective 2/3/21]

657—10.39(124) Temporary designation of controlled substances.

10.39(1) Amend Iowa Code section 124.206(6)*"c"* to read as follows:

c. Immediate precursors to fentanyl:

(1) 4-anilino-N-phenthyl-4-piperidine (ANPP).

(2) N-phenyl-N-(piperidin-4-yl)propionamide (norfentanyl).

10.39(2) Amend Iowa Code section 124.210(3) by adding the following new paragraphs:

be. Lemborexant.

bf. Remimazolam.

10.39(3) Amend Iowa Code section 124.212(5) by adding the following new paragraph:

e. ([(1R)-1-(2-chlorphenyl)-2-(tetrazol-2-yl)ethyl] carbamate; 2H-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alphaR)-; carbamic acid (R)-(+)-1-(2-chlorophenyl)-2-(2H-tetrazol-2-yl)ethyl ester. Other name: cenobamate.

10.39(4) Amend Iowa Code section 124.212 by rescinding subsection 6.

10.39(5) Amend Iowa Code section 124.204(9) by adding the following new paragraph:

ay. N,N-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (other names: isotonitazene; N,N-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1H-benzimidazole-1-ethanamine).

10.39(6) Amend Iowa Code section 124.206(3) by adding the following new paragraph:

ad. Oliceridine.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 3860C**, IAB 6/20/18, effective 7/25/18; **ARC 3984C**, IAB 8/29/18, effective 10/3/18; **ARC 4085C**, IAB 10/24/18, effective 10/3/18; **ARC 4269C**, IAB 1/30/19, effective 3/6/19; **ARC 4455C**, IAB 5/22/19, effective 6/26/19; **ARC 4797C**, IAB 12/4/19, effective 1/8/20; **ARC 4904C**, IAB 2/12/20, effective 3/18/20; **ARC 5346C**, IAB 12/30/20, effective 2/3/21; **ARC 5347C**, IAB 12/30/20, effective 2/3/21; **ARC 5541C**, IAB 4/7/21, effective 5/12/21]

657—10.40(124) Excluded and exempt 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. With the exception of listed butalbital products, the board hereby excludes from all schedules the current list of "Exempted Prescription Products" described in Title 21, CFR Part 1308, Section 32. Copies of such lists may be obtained by written request to the board office at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4455C**, IAB 5/22/19, effective 6/26/19]

657—10.41(124) Anabolic steroid defined. Anabolic steroid, as defined in Iowa Code section 126.2(2), includes any substance identified as such in Iowa Code section 124.208(6) or 126.2(2).

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.42(124B) Additional precursor substances. Rescinded **ARC 5346C**, IAB 12/30/20, effective 2/3/21.

657—10.43(124) Reporting discipline and criminal convictions. A registrant shall provide written notice to the board of any disciplinary or enforcement action imposed by any licensing or regulatory authority on any license or registration held by the registrant no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. A registrant shall provide written notice to the board of any criminal conviction of the registrant or of any owner that is related to the operation of the registered location no later than 30 days after the conviction. The term criminal conviction includes instances when the judgment of conviction or sentence is deferred.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17]

657—10.44(124) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a registration for any of the following:

1. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act.
2. Any conviction of a crime related to controlled substances committed by the registrant, or if the registrant is an association, joint stock company, partnership, or corporation, by any managing officer.
3. Refusing access to the registered location or registrant records to an agent of the board for the purpose of conducting an inspection or investigation.
4. Failure to maintain registration pursuant to 657—Chapter 10.

5. Any violation of Iowa Code chapter 124, 124B, 126, 155A, or 205, or any rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

[**ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

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, 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:

"Adulterated" means any drug or device that consists in whole or in part of any filthy, putrid, or decomposed substance.

"Ambulance service" means any privately or publicly owned service program that utilizes ambulances, including air transport vehicles, in order to provide patient transportation and emergency medical services.

"Authorized prescriber" means any provider who has prescriptive authority in the state of Iowa.

"Board" means the board of pharmacy.

"Bureau" means the Iowa department of public health, bureau of emergency and trauma services (BETS).

"Controlled substance" means any drug that is identified in Schedules I through V of Iowa Code chapter 124, the Iowa uniform controlled substances Act.

"CSA registration" means a registration issued by the board pursuant to Iowa Code chapter 124, the Iowa uniform controlled substances Act.

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

"DEA registration" means a registration issued by the DEA pursuant to 21 CFR Part 1301.

"Department" means the Iowa department of public health.

"Drug" means a substance as defined in Iowa Code section 155A.3(40) but does not include nonmedicated intravenous solutions such as saline.

"Emergency medical care provider" means an emergency medical care provider as defined in 641—131.1(147A).

"Emergency medical services" or *"EMS"* means an integrated medical care delivery system to provide emergency and nonemergency medical care.

"Emergency medical technician" or *"EMT"* means any emergency medical technician or EMT as defined in 641—131.1(147A).

"Medical direction" means direction, advice, or orders provided, in accordance with written parameters and protocols, to emergency medical care personnel by a medical director, supervising physician, or physician designee.

"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.

"Medical director-based" means that ownership of the drugs maintained in and used by the service program remains with the medical director.

"Patient care report" means a computerized or written report that documents the assessment and management of the patient by the emergency medical care provider.

"Pharmacy-based" means that ownership of the drugs maintained in and used by the service program remains with the pharmacy.

"Physician" means any individual licensed under Iowa Code chapter 148, 150, or 150A.

"Physician assistant" or *"PA"* means any individual licensed under Iowa Code chapter 148C.

"Primary program site" means the physical location from which the service program is operated and at which stock supplies of prescription drugs may be maintained and distributed to a program vehicle and a program substation.

"Program substation" means the physical location from which a service program is operated as a branch or extension of a primary program site, at which an emergency kit or supply of prescription drugs is maintained, and at which a stock supply of prescription drugs is not maintained.

"Protocols" means written direction and orders, consistent with the department's standard of care, that are to be followed by an emergency medical care provider in emergency and nonemergency

situations. Protocols shall be approved by the service program's medical director and shall address the care of both adult and pediatric patients.

"Responsible individual" means the individual who maintains legal responsibility of the prescription drugs and devices. "Responsible individual" includes the medical director in a medical director-based service program or the pharmacist in charge in a pharmacy-based service program.

"Service" or *"service program"* means any medical care ambulance service or nontransport service that has received authorization from the department.

"Service director" means the individual who is responsible for the operation and administration of a service program.

"Supervising physician" means any physician licensed under Iowa Code chapter 148, 150, or 150A who supervises and is responsible for medical direction of emergency medical care personnel when such personnel are providing emergency medical care.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 0342C**, IAB 10/3/12, effective 11/7/12; **ARC 3101C**, IAB 6/7/17, effective 7/12/17; Editorial change: IAC Supplement 9/8/21]

657—11.2(124,147A,155A) Responsibility. Each service program shall appoint a service director at the primary program site and shall have a responsible individual who is responsible for ensuring that the management of all prescription drugs complies with federal and state laws and regulations. In service programs that maintain both a pharmacy-based service program agreement and a medical director-based service program agreement, the responsible individual for each service program agreement shall be responsible for ensuring the management of drugs under that individual's ownership. If more than one pharmacy enters into an agreement with a pharmacy-based service program, the pharmacist in charge at each pharmacy is responsible for the rules and laws pertaining to the specific prescription drugs, including controlled substances, that each pharmacy provides to the service program.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.3(124,147A,155A) Registration required. In any service program which intends to provide services in or into Iowa that include the administration of controlled substances, the responsible individual shall ensure that each primary program site, regardless of location, is registered with the board pursuant to this rule. The current registration certificate shall be available at the primary program site for inspection and copying by the board, its representative, or any other authorized individual.

11.3(1) *Medical director-based service program.* In a medical director-based service program, CSA and DEA registrations shall be obtained for each primary program site in the name of the medical director. CSA and DEA registrations shall be obtained prior to procurement of any controlled substances for use in the service program. Separate registrations for program substations shall not be required. In a medical director-based service program, a CSA registration shall also be obtained in the name of the service program, shall secondarily name the medical director, and shall be issued for the address of the service program's primary program site.

11.3(2) *Pharmacy-based service program.* In a pharmacy-based service program, the CSA registration shall be issued in the name of the service program and shall secondarily name the provider pharmacy. The CSA registration shall be issued for the address of the service program's primary program site and shall identify the pharmacist in charge of the provider pharmacy as the individual responsible for the controlled substances at the service program. A pharmacy-based service program that is owned by and physically located at the same address as an Iowa-licensed and -registered hospital may, but is not required to, obtain a separate registration.

11.3(3) *Combination pharmacy-based and medical director-based service program.* In a service program that is a combination of pharmacy-based and medical director-based and both the pharmacy and medical director provide controlled substances, each provider of controlled substances shall maintain a CSA registration with the board as provided by this rule. A medical director-based program shall also maintain a federal DEA registration as provided by this rule.

11.3(4) *Change of address of registered primary program site.* A registrant shall apply to change the address of the registered primary program site by submitting a completed application and fee as provided in 657—subrule 10.9(2).

11.3(5) *Discontinuation of medical director in a medical director-based service program.* If a medical director intends to terminate a written agreement with a service program pursuant to rule 657—11.5(124,147A,155A), the medical director shall provide written notification to the board at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309, pursuant to 657—subrule 10.9(7), to cancel the registration, including the effective date of the termination of the agreement. The registration certificate shall be returned to the board no later than ten days following the effective date of the termination of the agreement.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17; **ARC 3637C**, IAB 2/14/18, effective 3/21/18; **ARC 3861C**, IAB 6/20/18, effective 7/25/18; Editorial change: IAC Supplement 9/8/21]

657—11.4(124,147A,155A) Written agreement. A signed, written agreement for the service program shall be maintained at the primary program site and be available for inspection and copying by the board, its representative, or any other authorized individual.

11.4(1) *Pharmacy-based service programs.* An Iowa-licensed pharmacy may enter into an agreement with a service program located in the state. The agreement with the service program shall establish that the service program is operating as an extension of the pharmacy with respect to the prescription drugs the pharmacy provides to the service program. The agreement shall be signed by the pharmacist in charge and the service director at the primary program site. A copy of this agreement shall be maintained at both the pharmacy and the primary program site while the agreement is in effect. Nothing in this rule prohibits more than one pharmacy from entering into an agreement with a service program provided that each pharmacy complies with all rules and regulations for a pharmacy-based service program, including maintenance of all required records specific to each pharmacy's drugs.

11.4(2) *Medical director-based service programs.* An Iowa-licensed physician may enter into an agreement with a service program located in the state. The agreement shall be signed by the medical director and the service director and be maintained at the primary program site while the agreement is in effect. The agreement shall include an attestation that the medical director agrees to abide by these rules.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.5(124,147A,155A) Termination of agreement. A written agreement may be terminated at the discretion of either the service program or the party or parties responsible for providing drugs to the service program. Written notification of such termination shall be provided to the other party at least 30 days prior to termination of the agreement.

11.5(1) *Pharmacy-based service programs.* Immediately upon discontinuation of a written agreement, all controlled substances shall be jointly inventoried by the pharmacist in charge of the pharmacy that owns the drugs and the service director or their respective designees. A record of this inventory shall be maintained at the pharmacy for two years from the date of the inventory and shall be available for inspection and copying by the board, its representative, or any other authorized individual. All drugs and devices that are the property of the pharmacy shall be immediately returned to the pharmacy.

11.5(2) *Medical director-based service programs.* Immediately upon discontinuation of a written agreement, all controlled substances shall be jointly inventoried by the medical director and the service director or their respective designees. A record of this inventory shall be maintained by the medical director for two years from the date of the inventory and shall be available for inspection and copying by the board, its representative, or any other authorized individual. All drugs and devices that are the property of the medical director shall be immediately returned to the medical director.

11.5(3) *Transfer of ownership.* If drugs in a service program are to be maintained under the ownership of a new pharmacy or medical director, such transfer of ownership shall be in compliance with 657—Chapter 10, 657—Chapter 17, and federal laws and regulations. Pursuant to rule 657—10.17(124), the transfer of Schedule II controlled substances shall require an executed DEA Form 222.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 0342C**, IAB 10/3/12, effective 11/7/12; **ARC 3101C**, IAB 6/7/17, effective 7/12/17; Editorial change: IAC Supplement 9/8/21]

657—11.6(124,147A,155A) Registration required. Rescinded **ARC 3101C**, IAB 6/7/17, effective 7/12/17.
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11]

657—11.7 Reserved.

657—11.8(124,147A,155A) Identification. A log of employees who have access to prescription drugs and to records regarding procurement, storage, and administration of prescription drugs at the service program shall be maintained for two years and be available for inspection and copying by the board, its representative, or any other authorized individual. This log shall include each employee's printed name and signature, printed and signed initials or other unique identification used in service program records, and the employee's level of certification. A service program may maintain an electronic record of employee identification, including the employee's name, signature, unique identification used in the service program records, and level of certification. Such log shall be maintained at the primary program site for at least two years from the date of the employee's last date of employment with the service program and shall be available for inspection and copying by the board, its representative, or any other authorized individual.
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.9 Reserved.

657—11.10(124,147A,155A) Ownership of prescription drugs. All prescription drugs obtained for use in a service program shall be owned either by a pharmacy or by the medical director of the service program.

11.10(1) *Pharmacy-based service programs.* If the drugs are owned by a pharmacy or more than one pharmacy pursuant to these rules, the service program shall be considered a pharmacy-based service program and shall comply with these rules as they pertain to a pharmacy-based service program.

11.10(2) *Medical director-based service programs.* If the drugs are owned by the medical director, the service program shall be considered a medical director-based service program and shall comply with these rules as they pertain to a medical director-based service program.

11.10(3) *Combination pharmacy-based and medical director-based service programs.* If the service program has entered into both pharmacy-based and medical director-based service program agreements, both the pharmacy and the medical director shall retain separate ownership of the prescription drugs supplied and shall comply with these rules as applicable. The primary program site shall maintain a list that identifies which prescription drugs are owned and supplied by each responsible individual.

11.10(4) *Transfer of ownership.* Any transfer of ownership of prescription drugs and devices in a service program shall be in compliance with 657—Chapter 10, 657—Chapter 17, and federal laws and regulations.
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.11(124,147A,155A) Policies and procedures.

11.11(1) The service director, the medical director, and the responsible individual shall develop, implement, and adhere to written policies and procedures for the operation and management of the service program with respect to prescription drugs and devices in accordance with these rules. These policies and procedures shall be available for inspection and copying by the board, its representative, or any other authorized individual. The policies and procedures shall be periodically reviewed by the responsible individual, the medical director, and the service director and shall identify the frequency of the review. Documentation of the review shall be maintained.

11.11(2) The policies and procedures shall address, at a minimum, the following:

a. Storage of drugs at the primary program site and any program substations, including appropriate temperature controls , temperature monitoring and response when drugs are exposed to extreme temperatures pursuant to rule 657—11.13(124,147A,155A).

b. Storage of drugs at the primary program site and any program substations, including adequate security to prevent diversion and unauthorized access to drugs and records pursuant to rule 657—11.13(124,147A,155A).

c. Protocols for administration of drugs pursuant to rule 657—11.14(124,147A,155A).

d. Administration of drugs outside the parameters of written protocols pursuant to rule 657—11.15(124,147A,155A).

e. Service program personnel matters including, but not limited to:

(1) Access to prescription drugs and records, identifying level of access based upon employee certification level and scope of practice.

(2) Authority to administer drugs based upon employee certification level and scope of practice.

(3) Authority to order, receive, and distribute prescription drugs and devices.

(4) Initial training and periodic review of the medication policies and procedures.

(5) Identification of registered nurses not employed by the service program who are authorized by the medical director pursuant to Iowa Code section 147A.12 and pursuant to rules of the board of nursing to provide emergency care under the service program's protocol.

f. Process for the return of drugs pursuant to rule 657—11.22(124,147A,155A).

g. Out-of-date and adulterated drugs pursuant to rule 657—11.23(124,147A,155A).

h. Drug and device recalls pursuant to rule 657—11.24(124,147A,155A).

i. Monthly inspections pursuant to rule 657—11.20(124,147A,155A).

j. Record retention as described in rule 657—11.34(124,147A,155A) and other applicable rules of the board.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 0342C**, IAB 10/3/12, effective 11/7/12; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.12 Reserved.

657—11.13(124,147A,155A) Storage. Prescription drugs at primary program sites and program substations shall be stored in designated secure areas that are clean and free of debris, where temperature is appropriately controlled, and in a manner to protect identity and integrity.

11.13(1) *Temperature.* Each drug shall be stored within the temperature range required in the manufacturer labeling. The service program shall utilize a method to provide continuous temperature control or monitoring, such as a temperature indicator, which at a minimum identifies when the drugs have been exposed to extreme temperatures. The service program shall regularly, but at least weekly, verify and document verification that the drugs have not been exposed to extreme temperatures. Drugs that are subjected to extreme temperatures shall not be administered to patients and shall be quarantined and returned to the responsible individual for disposition. Extreme temperatures shall be defined as excessive heat greater than 40 degrees Celsius (104 degrees Fahrenheit) and, if the product requires protection from freezing temperatures, excessive cold less than -10 degrees Celsius (13 degrees Fahrenheit). Disposition of unusable drugs shall be in compliance with rule 657—11.32(124,147A,155A).

11.13(2) *Security.* The security of prescription drugs, records for such drugs, and patient records is the responsibility of the responsible individual and shall provide for the effective control against theft of, diversion of, or unauthorized access to drugs and records. Policies shall identify procedures that will utilize or require the signature of two service employees for each disbursement to ensure accountability for controlled substances.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.14(124,147A,155A) Protocols. Every service program shall utilize department protocols as the standard of care. The service program medical director may authorize an alternative protocol provided the directives are within the EMS provider's scope of practice, are within acceptable medical practice, and have been filed with the department. Prescription drugs shall be administered pursuant only to a written protocol or oral order by an authorized prescriber. A copy of the current protocol shall be provided to and maintained by the responsible individual, the service director, the primary program site and each

program substation and shall be available for inspection and copying by the board, its representative, or any other authorized individual.
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17; Editorial change: IAC Supplement 9/8/21]

657—11.15(124,147A,155A) Administration of drugs beyond the limits of a written protocol. Drugs may be administered beyond the limits of a written protocol provided that medical direction from an authorized prescriber has been obtained prior to administration. The authorization shall be recorded in the patient care report documenting the identity of the authorizing prescriber. If an agent of the authorized prescriber relayed the order, the identity of the prescriber's agent, including the agent's first and last names and title, shall also be recorded. The administration of a Schedule II controlled substance in a pharmacy-based service program shall be documented pursuant to rule 657—11.16(124,147A,155A).
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.16(124,147A,155A) Administration of Schedule II controlled substances—pharmacy-based service program. In a pharmacy-based service program, Schedule II controlled substances may be administered to patients under the care of a service program, including administration beyond the limits of a protocol when authorized pursuant to rule 657—11.15(124,147A,155A), provided that a signed order is delivered by the authorized prescriber to the pharmacy within seven days of the date administration was authorized. The signed order shall contain all of the prescription information required pursuant to Iowa Code section 155A.27. The patient care report may be accepted as the required signed order if the patient care report includes the required prescription information, including an original signature of the authorizing prescriber.
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.17 and **11.18** Reserved.

657—11.19(124,147A,155A) Patient care reports. Patient care reports shall be maintained at the primary program site or the program substation as required by the bureau and rule 657—11.34(124,147A,155A).
[**ARC 9786B**, IAB 10/5/11, effective 11/9/11]

657—11.20(124,147A,155A) Prescription drugs in service programs. Prescription drugs maintained by a service program shall be owned by an Iowa-licensed pharmacy or the service program's medical director.

11.20(1) *Pharmacy-based service programs.* The pharmacist in charge, the medical director, and the service director shall jointly develop, consistent with the service program's protocol, a list of drugs to be maintained for administration by the service program. The pharmacy shall maintain a current list of all prescription drugs including controlled substances that the pharmacy maintains at the primary program site and at any program substation.

a. Replenishment. The responsible individual, the service director, or designee may request that replenishment supplies of drugs be maintained at the primary program site provided that the pharmacy has been supplied with administration records justifying the order. Records of the administration of Schedule III, IV, and V controlled substances and noncontrolled prescription drugs provided to and maintained at the pharmacy shall include, at a minimum: the patient's name; the name, strength, dosage form, and quantity of the drug administered; and the date of administration. Records of the administration of Schedule II controlled substances provided to and maintained at the pharmacy shall consist of a written prescription including all of the prescription information required pursuant to Iowa Code section 155A.27 or the patient care report if the patient care report includes the required prescription information, including an original signature of the authorizing prescriber. A pharmacist shall verify the accuracy of every drug to be disbursed to the primary program site. Documentation of this verification shall be maintained within the pharmacy records.

b. Replenishment using automated medication distribution system (AMDS). A pharmacy utilizing an automated medication distribution system (AMDS) may authorize replenishment of the service program's drug supplies from the AMDS provided that a pharmacist verifies the drugs stocked in

the AMDS component before the drugs are removed from the pharmacy. Service program personnel authorized to remove drugs from the AMDS for restocking the service program's supplies shall be assigned a unique identification and access code for the purpose of accessing the AMDS. Access by authorized service program personnel shall be restricted to specific drug products authorized for use by the service program. A pharmacist shall, within 72 hours, review the access of and removal of drugs from the AMDS by service program personnel and shall maintain documentation of that review within the pharmacy records.

c. *Inspections.* The pharmacist in charge shall ensure the completion of a monthly inspection of all prescription drugs maintained by the pharmacy at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. All drugs removed from service program stock shall be returned to the pharmacy. Records of inspection shall be maintained for two years from the date of the inspection at the pharmacy. The pharmacist in charge may delegate the completion of the monthly inspection to another pharmacist, a pharmacist-intern, a certified pharmacy technician, or another designee of the pharmacist in charge.

11.20(2) *Medical director-based service programs.* The medical director and the service director shall jointly develop, consistent with the service program's protocol, a list of drugs to be maintained for administration by the service program. The medical director shall maintain a current list of all prescription drugs including controlled substances that the medical director maintains at the primary program site and at any program substation.

a. *Replenishment.* All drugs procured for administration in a medical director-based service program shall be obtained from an Iowa-licensed wholesaler, pharmacy, or authorized prescriber.

b. *Inspections.* The medical director shall ensure the completion of a monthly inspection of all prescription drugs maintained by the medical director at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. Records of inspection shall be maintained for two years from the date of the inspection at the primary program site or the program substation. The medical director may delegate the completion of the required inspections to the service director or other designee.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 0342C**, IAB 10/3/12, effective 11/7/12; **ARC 1307C**, IAB 2/5/14, effective 3/12/14; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.21 Reserved.

657—11.22(124,147A,155A) Return of drugs. Drugs that have been removed from service program stock shall be returned to the responsible individual. In a pharmacy-based service program, drugs returned from the service program to the pharmacy may be used by the pharmacy for subsequent dispensing or administration provided the drugs are not outdated or adulterated. Records of the return of prescription drugs shall be maintained by the responsible individual for two years from the date of the return.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.23(124,147A,155A) Out-of-date drugs or devices. Any drug or device bearing an expiration date shall not be administered beyond the expiration date of the drug or device. Outdated drugs or devices shall be removed from service program stock and quarantined until such drugs or devices are returned to the responsible individual for disposition.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.24(124,147A,155A) Product recall. Each service program shall have a procedure for removal from service program stock all drugs or devices subject to a product recall. The procedure shall include action appropriate to the direction or requirements of the recall.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.25 Reserved.

657—11.26(124,147A,155A) Controlled substances records.

11.26(1) *Records maintained.* Every inventory or other record required to be maintained under this chapter, 657—Chapter 10, or Iowa Code chapter 124 shall be maintained at the primary program site or the program substation and by the pharmacy if the service program is pharmacy-based. All required records shall be available for inspection and copying by the board, its representative, or any other authorized individual for at least two years from the date of such record. Controlled substances records shall be maintained in a readily retrievable manner. Schedule II controlled substances records shall be maintained separately from all other records of the registrant.

11.26(2) *Receipt and disbursement records in medical director-based service programs.* Any pharmacy or other authorized registrant that provides controlled substances for a medical director-based service program shall provide to the service program a record of the disbursement and maintain a record of the disbursement pursuant to rule 657—10.16(124). The service program shall retain the record on which an authorized individual shall sign and record the actual date of receipt. The record 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.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17; **ARC 3637C**, IAB 2/14/18, effective 3/21/18]

657—11.27(124,147A,155A) Ordering Schedule II controlled substances—medical director-based service programs. A registrant authorized to order or distribute Schedule II controlled substances shall do so only pursuant to and in compliance with DEA regulations via a DEA Form 222 or via the DEA Controlled Substances Ordering System (CSOS).

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17; **ARC 3637C**, IAB 2/14/18, effective 3/21/18; **ARC 5349C**, IAB 12/30/20, effective 2/3/21]

657—11.28 Reserved.

657—11.29(124,147A,155A) Schedule II controlled substances perpetual inventory. Each service program located in Iowa that administers Schedule II controlled substances shall maintain a perpetual inventory for all Schedule II controlled substances pursuant to the requirements of this rule. All records relating to the perpetual inventory shall be maintained at the primary program site and shall be available for inspection and copying by the board, its representative, or any other authorized individual for a period of two years from the date of the record.

11.29(1) *Record.* The perpetual inventory record may be maintained in a hard-copy or 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. A record entry, once recorded, shall not be changed; any adjustments or corrections shall require entry of a separate record as provided in subrule 11.29(3).

11.29(2) *Information included.* The perpetual inventory record shall identify all receipts and disbursements of Schedule II controlled substances by drug name or by National Drug Code (NDC), including each patient administration, wastage, and return of a drug to the responsible individual. The record of receipt shall also identify the source of the drug, the strength and dosage form, the quantity, the date of receipt, and the name or unique identification of the individual verifying receipt of the drug.

The disbursement record shall identify where or to whom the drug is disbursed or administered, the strength and dosage form, the quantity, the date of disbursement or administration, and the name or unique identification of the individual responsible for the disbursement. Receipts and disbursements shall be recorded in the perpetual inventory as soon as practicable but no later than 24 hours after the receipt, disbursement, or administration.

11.29(3) *Adjustments or corrections to the record.* Any adjustments or corrections made to the perpetual inventory shall include the identity of the person making the adjustment or correction and the reason for the adjustment or correction.

11.29(4) *Reconciliation.* The pharmacist in charge or designee in a pharmacy-based service program, or the medical director or designee in a medical director-based service program, shall be responsible for reconciling the perpetual inventory record of all Schedule II controlled substances with the physical inventory at least monthly. Any discrepancy shall be reported within 24 hours of the discovery to the responsible individual for investigation.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.30(124,147A,155A) Controlled substances annual inventory. An accurate inventory shall be taken annually of all controlled substances maintained at the primary program site and program substations. Controlled substances in a pharmacy-based service program shall be included in the pharmacy's annual controlled substances inventory. The inventory record shall identify the drug name or National Drug Code (NDC) and the exact quantity under the control of the service program including drugs in replenishment stock and quarantined stock. The inventory record shall contain the date and time the inventory was taken and the printed name and signature of the individual or individuals responsible for the inventory record. Records of the inventory shall be maintained pursuant to rule 657—11.34(124,147A,155A).

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.31 Reserved.

657—11.32(124,147A,155A) Disposition of controlled substances. Disposition of controlled substances shall be pursuant to the requirements of this rule, rule 657—11.29(124,147A,155A), 657—Chapter 10, and federal regulations. Records shall be maintained at the primary program site and, if the service program is pharmacy-based, records shall be maintained at the pharmacy.

11.32(1) *Outdated, adulterated, or unwanted supply.* Controlled substances shall not be destroyed except as provided in subrule 11.32(2). Any drug that requires disposition shall be quarantined until the drug can be returned to the responsible individual. The responsible individual shall ensure the proper disposition of controlled substances according to the following procedures:

a. The responsible individual shall utilize the services of a DEA-registered and Iowa-licensed disposal firm (reverse distributor), or

b. The responsible individual shall utilize such other means determined and approved by the board.

11.32(2) *Administration wastage.* 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 may be destroyed or otherwise disposed of by the administering service program personnel, the medical director, or a pharmacist. Any wastage of a controlled substance shall be conducted in the presence of a responsible adult witness who is an authorized service program employee, a member of the professional or technician pharmacy staff, or a licensed health care professional. A written or electronic record of controlled substance wastage shall be created and maintained at the primary program site and, if the service program is pharmacy-based, at the pharmacy, for a minimum of two years following the disposition. The record shall include the signatures or other unique identification of the witness and of the individual destroying or otherwise disposing of the wastage of the controlled substance 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; and

e. If either individual involved in the wastage is not identified in the service program identification log, the legibly printed first and last names and title of the individual.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

657—11.33(124,147A,155A) Report of loss or theft of controlled substance. Upon suspicion of any loss or theft of a controlled substance, the service director shall immediately notify the responsible individual. The responsible individual shall provide notice and reporting as required in rule 657—10.21(124).

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17; **ARC 3637C**, IAB 2/14/18, effective 3/21/18]

657—11.34(124,147A,155A) Records. If a service program includes a primary program site and one or more program substations, each record shall identify the specific location to which it applies. Records regarding service program substation activities, including drug supply and administration records, may be maintained at the primary program site but shall clearly identify the program substation to which the records apply. All records regarding prescription drugs and devices in a service program shall be maintained for two years from the date of the activity or record and be available for inspection and copying by the board, its representative, or any other authorized individual.

[**ARC 9786B**, IAB 10/5/11, effective 11/9/11; **ARC 3101C**, IAB 6/7/17, effective 7/12/17]

These rules are intended to implement Iowa Code chapter 147A and Iowa Code sections 124.301 and 155A.13.

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[Editorial change: IAC Supplement 9/8/21]

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.

12.1(1) Amend Iowa Code section 124B.2(1) by adding the following new paragraphs:

a. N-(1-benzylpiperidin-4-yl)-N-phenylpropionamide (benzylfentanyl) and its salts.

b. N-phenylpiperidine-4-amine(4-anilinopiperidine; N-phenyl-4-piperidinamine; 4—AP), its amides, its carbamates, and its salts.

12.1(2) Reserved.

[**ARC 5346C**, IAB 12/30/20, effective 2/3/21]

657—12.2(124B) Reports required. Except as provided in rule 657—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 657—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 657—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 657—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 657—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 $180.

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 $180 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.
[**ARC 0504C**, IAB 12/12/12, effective 1/16/13]

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
TELEPHARMACY PRACTICE

657—13.1(155A) Purpose and scope. The purpose of this chapter is to provide standards for the provision of telepharmacy services to patients. These rules provide for pharmaceutical care services at a telepharmacy site utilizing audiovisual technologies that link the telepharmacy site with a managing pharmacy and one or more verifying pharmacists. The telepharmacy site and the managing pharmacy shall be located within Iowa and shall maintain appropriate licensure by the board.
[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.2(155A) Definitions. For purposes of this chapter, the following definitions shall apply:

"Board" means the board of pharmacy.

"CSA" or *"CSA registration"* means a registration issued pursuant to Iowa Code section 124.303 and 657—Chapter 10.

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

"Managing pharmacy" means a licensed pharmacy located in Iowa that oversees the activities of one or more telepharmacy sites.

"Telepharmacy" means the practice of pharmacy where pharmaceutical care services are provided using audiovisual technologies linking a telepharmacy site with the managing pharmacy.

"Telepharmacy site" means a licensed pharmacy that is operated by a managing pharmacy and staffed by one or more telepharmacy technicians where pharmaceutical care services, including the storage and dispensing of prescription drugs, drug utilization review, and patient counseling, are provided by a licensed pharmacist through the use of technology.

"Verifying pharmacist" means a remote Iowa-licensed pharmacist or pharmacists who perform any step in the prescription verification and dispensing process including but not limited to: verification of data entry; product selection, packaging, and labeling; drug utilization review; and patient counseling.
[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.3(124,155A) Written agreement. The managing pharmacy and the telepharmacy site shall execute and maintain a current written agreement between the pharmacies. If there is no current written agreement between the pharmacies, the telepharmacy site shall immediately notify the board and shall discontinue operations as a telepharmacy site until a current written agreement between the managing pharmacy and the telepharmacy site is executed.

13.3(1) *Contents of agreement.* The written agreement between the managing pharmacy and a telepharmacy site shall include, but may not be limited to, the following:

a. Staffing, to include telepharmacy technician staffing, verifying pharmacist staffing and availability, and on-site pharmacist staffing as needed.

b. Hours of operation of the telepharmacy site and hours of availability of pharmacists at the managing pharmacy.

c. Emergency contact information for the managing pharmacy and the telepharmacy site.

d. A complete description of the audiovisual technology to be utilized to link the managing pharmacy and the telepharmacy site.

e. A provision that, in the event that the telepharmacy technician is not available at the telepharmacy site, that a verifying pharmacist is not available, or that the audiovisual communication connection between the telepharmacy site and the managing pharmacy is not available, the telepharmacy site shall close pending the availability of the technician, the verifying pharmacist, and the communication link or pending the arrival at the telepharmacy site of a pharmacist to provide on-site pharmacy services.

f. Activities and services to be provided by the managing pharmacy at the telepharmacy site.

g. Identification of contact persons to receive, on behalf of the managing pharmacy and the telepharmacy site, notifications and official communications regarding the written agreement. Identification of contact persons shall include delivery addresses and preferred methods of delivery of

the written communications required by this rule and any other communications affecting the written agreement between the managing pharmacy and the telepharmacy.

h. Pharmacy locations, other than the managing pharmacy, where verifying pharmacists may be based or located.

13.3(2) *Termination of agreement.* A managing pharmacy shall provide written notice to the board and to the telepharmacy site 90 days in advance of the managing pharmacy's intent to terminate the agreement between the telepharmacy site and the managing pharmacy. A telepharmacy site shall provide written notice to the board and to the managing pharmacy 90 days in advance of the telepharmacy site's intent to terminate the agreement between the managing pharmacy and the telepharmacy site.

a. *New agreement.* A new written agreement between a managing pharmacy and the telepharmacy site, including the filing of a new pharmacy license application identifying the new pharmacist in charge, shall be executed within the 90-day advance notification period.

b. *No new agreement.* If the telepharmacy site is unable to contract with a new managing pharmacy, the telepharmacy site shall, 30 days prior to the expiration of the 90-day advance notification period, implement the prior notification requirements for closing a telepharmacy site as provided in subrule 13.3(3). The telepharmacy site shall cease operations and close at the end of that 30-day closing notification period unless a new written agreement is executed.

13.3(3) *Closing of telepharmacy site.* A telepharmacy site that intends to close the telepharmacy site shall provide written notification to the managing pharmacy and the board as provided in subrule 13.3(2). In addition, the telepharmacy site shall provide written notification to the DEA and to patients and shall comply with all requirements for closing a pharmacy as provided in 657—subrule 8.35(7).

13.3(4) *Closing of managing pharmacy.* A managing pharmacy that intends to close the managing pharmacy shall provide written notification to the telepharmacy site and the board as provided in subrule 13.3(2). In addition, the managing pharmacy shall provide written notification to the DEA and to patients and shall comply with all requirements for closing a pharmacy as provided in 657—subrule 8.35(7). A telepharmacy site that has been managed by the closing pharmacy shall comply with the provisions of subrules 13.3(2) and 13.3(3), as applicable.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.4(155A) Responsible parties. The responsibilities identified and assigned pursuant to rule 657—8.3(155A) shall be assigned, as appropriate, to the managing pharmacy and the telepharmacy site, by and through their respective owners or license holders, to the pharmacist in charge of each respective pharmacy and to staff pharmacists, including verifying pharmacists. A telepharmacy technician shall share responsibility with the pharmacist in charge of the telepharmacy site, the telepharmacy site, and the verifying pharmacist, as assigned in rule 657—8.3(155A), for all functions assigned to and performed by the telepharmacy technician.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17; **ARC 4798C**, IAB 12/4/19, effective 1/8/20]

657—13.5 to **13.7** Reserved.

657—13.8(124,155A) General requirements for telepharmacy site. The telepharmacy site shall maintain a pharmacy license issued by the board. If the telepharmacy site plans to dispense controlled substances, the telepharmacy site shall also maintain a CSA registration and a DEA registration.

13.8(1) *Located in Iowa.* A telepharmacy site shall be located within the state of Iowa.

13.8(2) *Pharmacist in charge.* The pharmacist in charge of the managing pharmacy shall designate a pharmacist in charge of the telepharmacy site pursuant to subrule 13.9(3).

13.8(3) *Security.* A telepharmacy site shall employ methods to prevent unauthorized access to prescription drugs, devices, and pharmacy and patient records. Such methods may include an alarm system and shall include other security systems and methods as provided by these rules. Alarm systems and entry system locks should be disarmed when the telepharmacy site is staffed and open for business. Minimum security methods shall include:

a. Electronic keypad or other electronic entry system into the telepharmacy site or the pharmacy department that requires and records the unique identification of the individual accessing the pharmacy,

including the date and time of access. Complete access records shall be maintained for a minimum of two years beyond the date of access.

b. Secure storage such as a safe.

c. Controlled access to computer records.

d. A continuous system of video surveillance and recording of the pharmacy department that includes maintenance of recordings for a minimum of 60 days following the date of the recording.

13.8(4) *Telepharmacy site signage.* In addition to the patient counseling sign required pursuant to subrule 13.8(5), one or more signs, prominently posted in every prescription pick-up area and clearly visible to the public, shall inform the public that the location is a telepharmacy site supervised by a pharmacist at a remote location. Signage shall include the name, location, and telephone number of the managing pharmacy. The telepharmacy site shall also prominently post the days and times that the telepharmacy is open for business.

13.8(5) *Patient counseling.* Patient counseling as required by rule 657—6.14(155A) shall be provided utilizing the audiovisual technology employed between the telepharmacy site and the managing pharmacy. Every telepharmacy site shall post in every prescription pickup area, in a manner clearly visible to patients, a notice that Iowa law requires the pharmacist to discuss with the patient any new prescriptions dispensed to the patient. The board shall provide a telepharmacy site with the required signage.

13.8(6) *Label requirements.* In addition to the label requirements identified in 657—subrule 6.10(1), the label affixed to or on the dispensing container of any prescription drug or device dispensed by a telepharmacy site pursuant to a prescription drug order shall include, on the primary label or affixed by use of an auxiliary label, the following:

a. The name, telephone number, and address of the telepharmacy site;

b. The name and telephone number of the managing pharmacy.

13.8(7) *Prohibited activities.* In the physical absence of a pharmacist, the following activities are prohibited:

a. Practice of pharmacist-interns or pharmacy support persons at the telepharmacy site, except that a pharmacy support person may deliver prescriptions to patients outside the telepharmacy site but may not engage in prescription delivery or any other activities at the telepharmacy site.

b. Advising patients regarding over-the-counter products unless that advice is communicated directly by a pharmacist to the patient.

c. Dispensing or delivering prescription medications packaged by a technician into patient med paks unless an on-site pharmacist has verified the drugs in the patient med paks.

d. Technician product verification program activities.

e. Compounding, unless an on-site pharmacist has verified the accuracy and completeness of the compounded drug product.

f. All judgmental activities identified in rule 657—3.23(155A) that a pharmacy technician is prohibited from performing in the practice of pharmacy.

13.8(8) *Continuous quality improvement.* A telepharmacy site shall implement and participate in a continuous quality improvement program pursuant to rule 657—8.26(155A).

13.8(9) *Technology failure.* If the audiovisual technology between the telepharmacy site and the managing pharmacy or the verifying pharmacist is not operational, no prescriptions shall be dispensed from the telepharmacy site to a patient unless a pharmacist is physically present at the telepharmacy site.

13.8(10) *Perpetual controlled substances inventory.* A telepharmacy site that dispenses controlled substances shall maintain a perpetual inventory record of those controlled substances.

a. The perpetual inventory record requirement shall apply to all controlled substances maintained and dispensed by the telepharmacy site and shall not be limited only to Schedule II controlled substances.

b. The perpetual inventory record format and other requirements provided in rule 657—10.18(124) shall apply to the telepharmacy site's perpetual inventory record of controlled substances, with the following exceptions:

(1) The perpetual inventory record shall contain records for all controlled substances, not just Schedule II controlled substances, and

(2) Audit of the perpetual inventory record shall be completed and the physical and perpetual inventories shall be reconciled pursuant to the requirements of 657—subrule 10.18(4) each month as part of the inspection of the telepharmacy site.

13.8(11) *Display of pharmacist license.* A telepharmacy site shall display, in a position visible to the public, the original license to practice pharmacy in Iowa of the pharmacist in charge of the telepharmacy site. The telepharmacy site shall display, in a position visible to the public, the current license renewal certificate, which may be a photocopy of an original renewal certificate, of the pharmacist in charge of the telepharmacy site and of each pharmacist who may provide patient counseling to patients at the telepharmacy site. A pharmacist working on site while the telepharmacy site is open to the public shall display an original license and current license renewal certificate pursuant to 657—subrule 8.4(1).

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17; **ARC 3862C**, IAB 6/20/18, effective 7/25/18; **ARC 4798C**, IAB 12/4/19, effective 1/8/20; **ARC 5007C**, IAB 3/25/20, effective 4/29/20; Editorial change: IAC Supplement 9/8/21]

657—13.9(155A) General requirements for managing pharmacy.

13.9(1) *Distance to telepharmacy site.* The managing pharmacy shall be located in Iowa and within a 200-mile radius of a telepharmacy site to ensure that the telepharmacy site is sufficiently supported by the managing pharmacy and that necessary personnel or supplies may be delivered to the telepharmacy site within a reasonable period of time of an identified need.

13.9(2) *Emergency preparedness plan.* A managing pharmacy shall develop and include in both the managing pharmacy's and the telepharmacy site's policies and procedures a plan for continuation of pharmaceutical services provided by the telepharmacy site in case of an emergency interruption of the telepharmacy site's services. The plan shall address the timely arrival at the telepharmacy site of necessary personnel or the delivery to the telepharmacy site of necessary supplies within a reasonable period of time following the identification of an emergency need. The plan may provide for alternate methods of continuation of the services of the telepharmacy site including, but not limited to, personal delivery of patient prescription medications from an alternate pharmacy location or on-site pharmacist staffing at the telepharmacy site.

13.9(3) *Pharmacist in charge.* The pharmacist in charge of the managing pharmacy shall designate a pharmacist in charge of the telepharmacy site, who will be identified on the license of the telepharmacy site. The pharmacist in charge of the telepharmacy site shall be employed by the managing pharmacy. Nothing in this subrule shall prohibit the pharmacist in charge of the managing pharmacy from simultaneously serving as the pharmacist in charge of the telepharmacy site.

13.9(4) *Adequate audiovisual connection.* The pharmacist in charge of the managing pharmacy shall ensure adequate audiovisual connection with the telepharmacy site during all periods when the telepharmacy site is open for business including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

13.9(5) *Monthly inspection.* The pharmacist in charge of the telepharmacy site or delegate pharmacist shall be responsible for performing a monthly inspection of the telepharmacy site. Inspection reports shall be signed by the individual pharmacist who performed the inspection. Inspection records and reports shall be maintained at the telepharmacy site for two years following the date of the inspection. A copy of the inspection report shall be provided to and maintained at the managing pharmacy. The monthly inspection shall include, but may not be limited to, the following:

a. Audit and reconciliation of controlled substances perpetual and physical inventories.

b. Audit of electronic entry system and records.

c. Verification that the video recording system is functioning properly and that the recordings are maintained and available for at least 60 days past the date of the recording.

d. Compilation of a record of the number of prescriptions filled, the number of on-site pharmacist hours, and the number of hours the pharmacy site was open for business during the preceding month.

e. Review of written policies and procedures and verification of compliance with those policies and procedures.

f. Ensuring compliance with and review of records in the continuous quality improvement program, following up with responsible personnel to address issues identified by incident reports to prevent future incidents.

g. Review of records of the receipt and disbursement of prescription drugs, including controlled substances, to ensure compliance with record-keeping requirements.

h. Inspection of drug supplies and storage areas to ensure removal and quarantine of outdated drugs.

i. Inspection of stock drug supplies and storage areas to ensure drugs are maintained in a manner to prevent diversion and maintain the integrity of the drugs, verifying that the temperatures of storage areas are appropriate for the stored drugs and equipment.

j. Inspection of pharmacy and storage areas and shelves to ensure areas and shelves are clean and free of pests and other contaminants.

13.9(6) *On-site pharmacist staffing.* In an effort to promote public health, the telepharmacy site shall be staffed by a pharmacist for at least 16 hours per month. While on site, the pharmacist shall make available to the community general health care services, which may include, but not necessarily be limited to, immunizations, medication therapy management, or health screenings, as deemed necessary and appropriate by the pharmacist in charge and as provided by policies and procedures.

a. If a pharmacist will be available at the telepharmacy site to provide in-person patient services, a consistent schedule of the pharmacist's availability shall be established and published.

b. Signage identifying the days and times when a pharmacist is on site and available to patients shall be conspicuously posted at the telepharmacy site and may be published by other means, as deemed appropriate.

c. Notice that the pharmacist will not be present at the telepharmacy site during any routinely scheduled and posted on-site availability shall be provided to the public in advance of the absence except as provided in the emergency preparedness plan.

d. If the average number of prescriptions dispensed per day by the telepharmacy site exceeds 150 prescriptions, the telepharmacy site shall provide on-site pharmacist staffing 100 percent of the time the pharmacy is open for business and shall, within ten business days, apply to the board for licensure as a general pharmacy. The average number of prescriptions dispensed per day shall be determined by averaging the number of prescriptions dispensed per day over the previous 90-day period.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17; **ARC 4798C**, IAB 12/4/19, effective 1/8/20]

657—13.10(155A) General requirements for verifying pharmacist. A verifying pharmacist shall maintain a current and active license to practice pharmacy in Iowa.

13.10(1) *Location of verifying pharmacist.* The verifying pharmacist who is performing patient counseling shall be physically located within the managing pharmacy or another pharmacy licensed to operate a pharmacy in Iowa.

13.10(2) *Adequate audiovisual connection.* The verifying pharmacist shall ensure adequate audiovisual connection with the telepharmacy site during all periods when the pharmacist is responsible for verifying telepharmacy site activities and practices, including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

13.10(3) *Verifying pharmacist training.* A verifying pharmacist shall be adequately trained on the use of the technology to ensure accurate verification and patient counseling and shall review and understand the policies and procedures of the managing pharmacy and the telepharmacy site.

13.10(4) *Patient refusal of counseling.* If a patient or patient's caregiver refuses patient counseling, the refusal shall be directly communicated by the patient or patient's caregiver to the pharmacist through audiovisual communication. A technician may not accept and communicate a refusal of patient counseling from the patient or patient's caregiver to the pharmacist.

13.10(5) *Reference library.* A verifying pharmacist shall have access to all required references applicable to the telepharmacy services provided at the telepharmacy site.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.11(155A) General requirements for telepharmacy technician. A telepharmacy technician shall maintain current national certification and registration in good standing with the board as a certified pharmacy technician.

13.11(1) *Practice experience.* Before practicing in a telepharmacy site, a telepharmacy technician shall have completed a minimum of 2,000 hours of practice experience as a certified pharmacy technician, at least 1,000 hours of which shall be practicing in an Iowa-licensed pharmacy and 160 hours of which shall be practicing in a managing pharmacy, at another pharmacy which uses the same audiovisual technology system, or at the telepharmacy site under the direct supervision of an on-site pharmacist.

13.11(2) *Training.* In addition to training required of all pharmacy technicians, a telepharmacy technician shall complete the following minimum training requirements before practicing in a telepharmacy site. Records of telepharmacy technician training shall be documented and maintained by the telepharmacy site.

a. Review and understanding of the policies and procedures of the managing pharmacy.

b. Review and understanding of the policies and procedures of the telepharmacy site.

c. Review and understanding of these rules for telepharmacy practice.

d. Review and understanding of pharmacy technician rules, 657—Chapter 3.

e. Understanding of the operation of the audiovisual technologies to be utilized at both pharmacies.

f. Training at the telepharmacy site under the direct supervision of an on-site verifying pharmacist. Training shall include operation and use of the audiovisual technology and other means of communication between the telepharmacy site and the managing pharmacy and all daily operations from unlocking and opening the telepharmacy site to closing and locking the telepharmacy site at the end of the business day. If the telepharmacy site is protected by one or more alarm systems, training shall include how to disarm and engage the alarm system or systems.

13.11(3) *Continuing education.* Beginning with the first full two-year continuing education period for renewal of the technician's national pharmacy technician certification after beginning practice as a telepharmacy technician, and for each subsequent renewal of national certification for as long as the technician continues to practice as a telepharmacy technician, the technician shall complete two hours of continuing education in each of the following activities. These continuing education requirements shall not be in addition to the total continuing education credits required to maintain national certification.

a. Patient safety/medication errors.

b. Pharmacy law.

13.11(4) *Identification.* The telepharmacy technician shall, at all times when the technician is practicing at the telepharmacy site and the telepharmacy site is open for business, wear a name badge or tag identifying the technician. The badge or tag shall include, at a minimum, the technician's first name and title. The name badge or tag shall be so designed and worn that the technician's name and title are clearly visible to the public at all times.

13.11(5) *Adequate audiovisual connection.* The telepharmacy technician shall ensure adequate audiovisual connection with the managing pharmacy during all periods when the telepharmacy site is open for business, including ensuring confidentiality of communications in compliance with state and federal confidentiality laws.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17; **ARC 4798C**, IAB 12/4/19, effective 1/8/20; Editorial change: IAC Supplement 9/8/21]

657—13.12 to **13.15** Reserved.

657—13.16(124,155A) Telepharmacy site—initial application.

13.16(1) *License application.* A telepharmacy site shall complete and submit to the board a limited use/telepharmacy license application and nonrefundable fee as provided in rule 657—8.35(155A). In addition to the application and fee, the telepharmacy site shall include the additional information identified in this rule.

13.16(2) *CSA registration application.* If controlled substances will be dispensed from the telepharmacy site, the telepharmacy site shall complete and submit, with the limited use/telepharmacy

license application and fee, the CSA registration application and nonrefundable fee as provided in rule 657—10.5(124).

13.16(3) *Identification of managing pharmacy.* The telepharmacy site application shall include identification of the managing pharmacy, including pharmacy name, license number, address, telephone number, and pharmacist in charge; a statement from the managing pharmacy or pharmacist in charge indicating that the managing pharmacy has executed a written agreement to provide the required services and oversight to the telepharmacy site; and a statement from the pharmacist in charge of the managing pharmacy designating the pharmacist in charge of the telepharmacy site pursuant to subrule 13.9(3).

13.16(4) *Distance to nearest pharmacy that dispenses prescription drugs to outpatients.* The telepharmacy site application shall identify the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients and shall provide evidence identifying the total driving distance between the proposed telepharmacy site and the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

a. If the distance between the proposed telepharmacy site and the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is less than ten miles, the telepharmacy site shall submit a request for waiver of the distance requirement. The process and requirements for a request for waiver are identified in subrule 13.16(8).

b. The distance requirement shall not apply under any of the following circumstances:

(1) The telepharmacy site was approved by the board and operating as a telepharmacy site prior to July 1, 2016.

(2) The proposed telepharmacy site is located within a hospital campus, and services will be limited to inpatient dispensing.

(3) The proposed telepharmacy site is located on property owned, operated, or leased by the state.

13.16(5) *Written agreement.* The telepharmacy site application shall include the written agreement between the telepharmacy site and the managing pharmacy as described in subrule 13.3(1).

13.16(6) *Key personnel.* The telepharmacy site application shall identify key personnel including the pharmacist in charge of the managing pharmacy, the pharmacist in charge of the telepharmacy site, and the telepharmacy technician or technicians at the telepharmacy site. Identification shall include the names, the license or registration numbers, and the titles of the key personnel. Telepharmacy technician identification shall also include a copy of the telepharmacy technician's current national certification or other verification of the telepharmacy technician's current national certification.

13.16(7) *Audiovisual technology.* A description of the audiovisual technology system to be used to link the managing pharmacy and the telepharmacy site, including built-in safeguards relating to verification of the accuracy of the dispensing processes. Safeguards shall include but may not be limited to:

a. Requiring a verifying pharmacist to review and compare the electronic image of any new prescription with the data entry record of the prescription prior to authorizing the telepharmacy site's system to print a prescription label and prior to the telepharmacy technician's filling of the prescription at the telepharmacy site.

b. Requiring the technician to use barcode technology at the telepharmacy site to verify the accuracy of the drug to be dispensed.

c. Requiring remote visual confirmation by a verifying pharmacist of the drug stock bottle and the drug to be dispensed prior to the dispensing of the prescription at the telepharmacy site.

d. Ensuring that the telepharmacy site's system prevents a prescription from being sold and delivered to a patient before the verifying pharmacist has performed a final verification of the accuracy of the prescription and released the prescription for sale and delivery at the telepharmacy site.

13.16(8) *Request for distance waiver.* The board shall consider a request for waiver of the distance requirement between the proposed telepharmacy site and the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients if the petitioner can demonstrate to the board that the proposed telepharmacy site is located in an area where there is limited access to pharmacy services and that there exist compelling circumstances that justify waiving the distance requirement.

a. The request for waiver shall be prepared and shall include the elements of a request for waiver identified in 657—Chapter 34.

b. In addition to the requirements of 657—Chapter 34, the request for waiver shall include evidence and specific information regarding each of the following, if applicable. If an item identified below does not apply to the proposed telepharmacy site, the request for waiver shall specifically state that the item does not apply.

(1) That the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is open for business for limited hours or fewer hours than the proposed telepharmacy site.

(2) That the proposed telepharmacy site intends to provide services not available from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

(3) That access to the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is limited. A description of how the proposed telepharmacy site will improve patient access to pharmacy services shall be included.

(4) That limited access to pharmacy services is affecting patient safety.

(5) That there are transportation barriers to services from the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients.

(6) That the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients is closing.

(7) That the proposed telepharmacy site is located in an area of the state where there is limited access to pharmacy services.

c. The board shall consider a request for waiver of the distance requirement during any open session of a meeting of the board. One or more representatives of the parties to the waiver request, including representatives of the proposed telepharmacy site, the managing pharmacy, and the nearest currently licensed pharmacy that dispenses prescription drugs to outpatients, shall be invited and encouraged to attend the meeting at which the waiver request is scheduled for consideration to be available to respond to any questions.

d. The board's decision to grant or deny the request for waiver of the distance requirement shall be a proposed decision and shall be reviewed by the director of the department of public health.

(1) The director shall have the power to approve, modify, or veto the board's proposed decision regarding the waiver request.

(2) The director's decision on a waiver request shall be considered final agency action.

(3) The director's decision (final agency action) shall be subject to judicial review under Iowa Code chapter 17A.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17; **ARC 4268C**, IAB 1/30/19, effective 3/6/19; **ARC 4798C**, IAB 12/4/19, effective 1/8/20; **ARC 5348C**, IAB 12/30/20, effective 2/3/21]

657—13.17(124,155A) Changes to telepharmacy site or managing pharmacy. Except as specifically provided by these rules, a change to a telepharmacy site shall require compliance with the licensure and notification requirements of the specific type of change identified in 657—subrules 8.35(6) and 8.35(7). A change affecting the CSA registration shall comply with the appropriate requirements of rule 657—10.9(124).

13.17(1) *Change of pharmacist in charge.* A change of pharmacist in charge at either the managing pharmacy or telepharmacy site shall require submission of a pharmacy license application for the respective pharmacy location as provided by 657—subrule 8.35(6) and rule 657—13.16(124,155A).

13.17(2) *Closing or selling of pharmacy.* A telepharmacy site or managing pharmacy that intends to close or sell the pharmacy practice shall comply with all requirements for closing or selling a pharmacy found at 657—subrules 8.35(6) and 8.35(7) regarding ownership change and closing a pharmacy, including all advance notification requirements. A purchaser of a telepharmacy site shall complete and submit applications and supporting information as provided in rule 657—13.16(124,155A). A closing pharmacy shall also comply with the requirements of subrule 13.3(3) or 13.3(4), as appropriate.

13.17(3) *Location change.* A telepharmacy site that intends to move to and to provide telepharmacy services from a new location that is outside the community wherein the telepharmacy site has been

located shall comply with the requirements of subrule 13.17(2) for closing a pharmacy and shall submit applications and supporting information as provided in rule 657—13.16(124,155A). A managing pharmacy that intends to move to a new location shall comply with the requirements of 657—subrules 8.35(4), 8.35(6), and 8.35(7), as appropriate.
[**ARC 3236C**, IAB 8/2/17, effective 9/6/17; **ARC 3858C**, IAB 6/20/18, effective 7/25/18; **ARC 4798C**, IAB 12/4/19, effective 1/8/20]

657—13.18(155A) Opening of traditional pharmacy. If a pharmacy licensed as a general, hospital, or limited use pharmacy opens for business within ten miles of an existing and operating telepharmacy site, the telepharmacy site may continue to operate as a telepharmacy site and shall not be required to close due to the proximity of the new pharmacy.
[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.19 and **13.20** Reserved.

657—13.21(124,155A) Policies and procedures. In addition to policies and procedures required for the specific services provided and identified in other chapters of board rules, both the managing pharmacy and the telepharmacy site shall develop, implement, and adhere to written policies and procedures for the operation and management of the specific pharmacy's operations.

13.21(1) *Minimum requirements.* Policies and procedures shall define the frequency of review, and written documentation of review by the respective pharmacist in charge shall be maintained. Policies and procedures shall address, at a minimum, the following:

a. Procedures ensuring that a record is made and retained identifying the pharmacist who verified the accuracy of the prescription including the accuracy of the data entry, the selection of the correct drug, the accuracy of the label affixed to the prescription container, and the appropriateness of the prescription container.

b. Procedures ensuring that a record is made and retained identifying the pharmacist who performed the drug utilization review as provided by rule 657—8.21(155A).

c. Procedures ensuring that a record is made and retained identifying the pharmacist who provided counseling to the patient or the patient's caregiver pursuant to rule 657—6.14(155A).

d. Procedures ensuring that a record is made and retained identifying the technician who filled the prescription.

e. Procedures ensuring adequate security to prevent unauthorized access to prescription drugs and devices and to confidential records.

f. Procedures regarding procurement of drugs and devices, including who is authorized to order or receive drugs and devices, from whom drugs and devices may be ordered and received, and the required method for documentation of the receipt of drugs and devices.

g. Procedures ensuring appropriate and safe storage of drugs at the telepharmacy site, including appropriate temperature controls.

h. Procedures identifying the elements of a monthly inspection of the telepharmacy site by the pharmacist in charge or designated pharmacist, including requirements for documentation and retention of the results of each inspection.

i. Procedures for the temporary quarantine of out-of-date and adulterated drugs from dispensing stock and the subsequent documented disposal of those drugs.

j. Procedures and documentation required in the case of return to the telepharmacy of a drug or device.

k. Procedures for drug and device recalls.

13.21(2) *Availability.* Policies and procedures shall be available for inspection and copying by the board or the board's representative at the location to which the policies and procedures apply.
[**ARC 3236C**, IAB 8/2/17, effective 9/6/17; **ARC 4798C**, IAB 12/4/19, effective 1/8/20]

657—13.22(155A) Reports to the board. The board may periodically request information regarding the services provided by a telepharmacy site.

13.22(1) *Timeliness.* A telepharmacy site shall complete and submit the requested information in a timely manner as requested by the board. The board shall allow a reasonable amount of time for a telepharmacy site to complete and submit the requested information.

13.22(2) *Information to include.* Information requested may include, but may not necessarily be limited to, the following:

a. The number of prescriptions dispensed from the telepharmacy site over a specified period of time.

b. The number of hours a pharmacist was physically present at the telepharmacy site over a specified period of time.

c. The number of hours the telepharmacy site was open for business over a specified period of time.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

657—13.23(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 telepharmacy site 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 substances records shall be maintained in a readily retrievable manner in accordance with federal requirements and 657—Chapter 10.

13.23(1) *Dispensing record.* As provided in rule 657—13.21(124,155A), a written or electronic record identifying the pharmacist who verified the prescription, the pharmacist who provided counseling to the patient or the patient's caregiver, and the pharmacy technician who filled the prescription shall be maintained for every prescription fill dispensed by the telepharmacy site.

13.23(2) *On-site pharmacist staffing.* A written or electronic record of the number of prescriptions filled, the number of on-site pharmacist hours, and the number of hours the telepharmacy site was open for business each month shall be maintained by the telepharmacy site.

13.23(3) *Pharmacy access.* Records identifying, by unique identification of the individual accessing the pharmacy department, including the date and time of access, shall be maintained for two years beyond the date of access.

13.23(4) *Monthly inspection.* Reports of the monthly inspection of the telepharmacy site shall be maintained at the telepharmacy site for two years following the date of the inspection. A copy of the inspection report shall be provided to and maintained at the managing pharmacy for two years following the date of the inspection.

[**ARC 3236C**, IAB 8/2/17, effective 9/6/17]

These rules are intended to implement Iowa Code sections 124.301, 147.107, 155A.3, 155A.6A, 155A.13, 155A.14, 155A.19, 155A.28, 155A.31, 155A.33, and 155A.41.

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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 657—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 657—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 657—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 657—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 657—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 657—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', pharmacy technicians', and pharmacy support persons' names, addresses, or employment changes. This information is collected by the board pursuant to the authority granted in Iowa Code sections 155A.6, 155A.6A and 155A.19 and 2009 Iowa Code Supplement section 155A.6B 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.

14.14(17) *Pharmacy support person records.* These records contain information about pharmacy support persons who are registered with the board. This information is collected by the board pursuant to the authority granted in Iowa Code chapter 155A and is stored on paper, electronically, and in computer.
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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 657—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 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 patients in correctional facilities from one or more correctional pharmacies. Each correctional pharmacy shall be responsible for the provision of pharmacy services for a specific number of correctional facilities. The correctional pharmacies may be located on the grounds of a correctional facility or may be located off site from all facilities. The correctional pharmacies shall be licensed by the board with limited-use pharmacy licenses designated as correctional pharmacy licenses. Pharmacists shall be responsible for any delegated act performed by supportive personnel under the pharmacists' supervision. The requirements of these rules for correctional 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.
[**ARC 8670B**, IAB 4/7/10, effective 5/12/10]

657—15.2(126,155A) Definitions. For purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Department" means the Iowa department of corrections.

"Emergency/first dose drug supply" means a limited inventory of drugs stored outside the correctional pharmacy and accessible to designated health care staff for the purpose of initiating emergency or first dose prescription drug orders issued during periods when the pharmacist is unavailable.

"Medication administration record" means the record of the administration of drugs to patients.

"Med-pak" means 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.

"Prescription drug order" means an order that is for a drug or device for a patient in custody status in a correctional facility, that is originated by a practitioner authorized to prescribe, and that meets the information requirements for a prescription drug order but is recorded, distributed, and administered as though it were a medication order.

"Qualified individual" means a pharmacist, a person who has successfully completed a medication administration course, or a person specifically authorized under pertinent sections of the Iowa Code to administer prescription drugs.

"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.
[**ARC 8670B**, IAB 4/7/10, effective 5/12/10]

657—15.3(155A) Responsibilities. In any correctional pharmacy, the following responsibilities, which are in addition to the responsibilities required by all applicable federal and state laws, rules and regulations and the responsibilities as described in rule 657—8.3(155A), shall be assigned as follows:

1. The pharmacist in charge or designee shall ensure that a quarterly inspection of all pharmaceuticals located at the correctional facility, including any emergency/first dose drug supply located outside the confines of the pharmacy, is completed and documented.

2. The pharmacist in charge or a pharmacist shall provide drug information to other health professionals, to other caregivers, and to patients as required or requested.
[**ARC 8670B**, IAB 4/7/10, effective 5/12/10; **ARC 1961C**, IAB 4/15/15, effective 5/20/15]

657—15.4(155A) Reference library. Each correctional pharmacy shall maintain a reference library, which is either printed or computer-accessed and which adequately meets the needs of the services provided and patients served. Examples of references include:

1. A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice.
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 drug 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 relating to specific patient populations served.

[**ARC 8670B**, IAB 4/7/10, effective 5/12/10; **ARC 2196C**, IAB 10/14/15, effective 11/18/15; **ARC 4073C**, IAB 10/10/18, effective 11/14/18]

657—15.5(124,155A) Security. The pharmacy shall be located in an area or areas that provide for effective control against theft of, diversion of, and unauthorized access to prescription drugs and pharmacy records. The following conditions shall be met to ensure appropriate control over drugs and chemicals in the pharmacy:

15.5(1) *Locked areas.* All areas occupied by the correctional 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.* Pursuant to rule 657—8.3(155A), the pharmacy shall have policies and procedures for the security of the correctional pharmacy. Policies and procedures shall identify who will have access to the pharmacy, what areas may be accessed, and the procedures to be followed for obtaining drugs and chemicals when the pharmacist is absent from the pharmacy.

15.5(3) *Pharmacist responsibility.* Each pharmacist, while on duty, shall be responsible for the security of the correctional pharmacy. 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). A pharmacist shall be on site during all times that the pharmacy is open.

15.5(4) *Drugs in the correctional facility.* All drugs distributed from the pharmacy to areas of the correctional facility for subsequent administration to patients shall be kept in locked storage when not in use. Policies and procedures shall identify the qualified individuals who are authorized to access these drugs and the process to be followed for their removal.

[**ARC 8670B**, IAB 4/7/10, effective 5/12/10; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 4073C**, IAB 10/10/18, effective 11/14/18]

657—15.6 Reserved.

657—15.7(124,126,155A) Training and utilization of pharmacy technicians or pharmacy support persons. Pharmacy technician and pharmacy support person training shall be documented and maintained by the pharmacy for at least two years from the last date of employment. Policies and procedures and documentation of pharmacy technician and pharmacy support person training shall be available for inspection by the board or an agent of the board.

[**ARC 8670B**, IAB 4/7/10, effective 5/12/10; **ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 4073C**, IAB 10/10/18, effective 11/14/18]

657—15.8(124,126,155A) Drug distribution and dispensing controls. Prescription drugs shall be distributed or dispensed only from the original or a properly verified prescription drug order. There shall be no transcribing of prescription drug orders by nursing staff or clerical staff except for their own records.

15.8(1) *Required information.* Prescription drug orders written in patient health records shall include the following information:

a. Patient name, identification number, and correctional facility location;

b. Drug name, strength, dosage form, and quantity or duration;

c. Directions for use of the drug;

d. Date the prescription drug order is authorized;

e. Prescriber's name, signature or electronic signature, and office address;

f. Prescriber's DEA number for controlled substances.

15.8(2) *Original maintained.* The original prescription drug order and the medication administration record shall be maintained for a minimum of two years in the patient's health record.

15.8(3) *Effect upon transfer of patient.* Current prescription drug orders remain in effect when a patient is transferred to another correctional facility.

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 by pharmacy staff in compliance with the provisions of rule 657—22.1(155A). Policies and procedures shall be implemented that include, but are not limited to, the following:

a. Return and reuse of drugs;

b. Expiration dating;

c. Record keeping.

15.8(5) *Med-pak dispensing.* Drugs may be dispensed in med-pak dispensing systems for subsequent administration by nurses or other qualified individuals. Policies and procedures shall be implemented that are in accordance with rule 657—22.5(155A) and include, but are not limited to, the following:

a. Return and reuse of containers;

b. Expiration dating;

c. Record keeping.

15.8(6) *Drug administration.* Only a licensed health care professional authorized to administer drugs or a qualified individual shall administer to a patient prepackaged drugs from the supply distributed by the pharmacy. Documentation of administration shall be recorded in the medication administration record. The single unit, unit dose, or med-pak packaging shall remain intact to the point of administration.

15.8(7) *Dispensing for patient self-administration.* Drugs dispensed for self-administration by a patient shall be packaged and labeled in accordance with rule 657—6.10(126,155A).

15.8(8) *Labeling of drugs under special circumstances.*

a. Insulin, ophthalmics, otic preparations, inhalers, nasal sprays, topicals, and other similarly packaged drugs. A label shall be affixed to the immediate container showing at least the patient's name and ID number. A label that complies with 657—subrule 6.10(1) shall be affixed to the outer container.

b. Leave and release drugs. Labeling of prescription drugs for patients leaving the correctional facility for temporary absences in excess of 24 hours, such as court appearances, and for patients being released from custody shall comply with 657—subrule 6.10(1) before the drug is removed from the facility. The dispensing pharmacy shall be responsible for packaging and labeling leave and release drugs in compliance with this paragraph.

15.8(9) *Drug product selection.* Correctional pharmacies shall be exempt from the patient notification requirements of Iowa Code section 155A.32 when exercising drug product selection.

15.8(10) *Emergency/first dose drug supply.* An emergency/first dose drug supply of prescription drugs may be supplied to a correctional facility for use by authorized personnel pursuant to rule 657—22.7(124,155A). Only pharmacists, pharmacist-interns, and pharmacy technicians may restock, replace, or return drugs to the emergency/first dose drug supply. A drug shall be removed from the emergency/first dose drug supply only pursuant to a valid prescription drug order. The pharmacy shall be notified of the removal and administration of a drug from the emergency/first dose drug supply. The pharmacist shall perform drug use review prior to the administration of a second dose. All drugs removed from the emergency/first dose drug supply that are not administered, including any wastage,

shall be returned to the pharmacy. A written or electronic record shall be made of all removals from the emergency/first dose drug supply. The record shall include the following information:

a. Patient's name and identification number;
b. Prescriber;
c. Name, strength, dosage form, and quantity of the drug removed;
d. Signature, unique identification, or initials of the authorized person removing the drug;
e. Date and time the drug was removed;
f. Returns of unused drugs to the pharmacy.

[**ARC 8670B**, IAB 4/7/10, effective 5/12/10; **ARC 4073C**, IAB 10/10/18, effective 11/14/18]

657—15.9 Reserved.

657—15.10(124,126,155A) Policies and procedures. Pharmacy policies and procedures, established, implemented, and complied with pursuant to rule 657—8.3(155A), 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. Leave and release drugs;
11. Emergency/first dose drug supply;
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 and correctional pharmacies;
18. Transfers of prescription drug orders between correctional pharmacies;
19. Delivery of drugs;
20. Notification when a drug or device is not available;
21. Drug destruction within the pharmacy;
22. Return of unused drugs.

[**ARC 8670B**, IAB 4/7/10, effective 5/12/10; **ARC 1961C**, IAB 4/15/15, effective 5/20/15]

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 124.308, 126.10, 126.11, 155A.6A, 155A.6B, 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. This chapter establishes the minimum standard for the practice of pharmacy relating to radioactive drugs. These rules apply to individuals authorized to receive, handle, transfer, dispense, or dispose of radioactive drugs pursuant to Iowa Code chapters 136C, 155A, and 455B, and rules of the board, the environmental protection commission, or the public health department. For pharmacies, these rules are in addition to other applicable chapters of rules of the board including, but not limited to, 657—Chapters 8 and 20.

[**ARC 3525C**, IAB 12/20/17, effective 1/24/18]

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.

"Authorized nuclear pharmacist" means a person currently licensed to practice pharmacy in Iowa who meets the qualifications established by rule 657—16.3(155A).

"Board" means the Iowa board of pharmacy.

"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.

"Radioactive drug" or *"radiopharmaceutical"* means a drug or device that contains a radioactive substance and is used to diagnose or treat disease.

"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.

[**ARC 3525C**, IAB 12/20/17, effective 1/24/18]

657—16.3(155A) Training requirements for authorized nuclear pharmacist. An authorized nuclear pharmacist shall meet all requirements of the United States Nuclear Regulatory Commission pursuant to federal regulations.

[**ARC 3525C**, IAB 12/20/17, effective 1/24/18]

657—16.4(155A) General requirements for a pharmacy providing radiopharmaceutical services. A pharmacy providing radiopharmaceutical services shall obtain a limited use pharmacy license pursuant to rule 657—8.35(155A) prior to commencing provision of services in this state.

16.4(1) *Authorized nuclear pharmacist.* The pharmacist in charge shall be an authorized nuclear pharmacist and shall be responsible for, at a minimum, the requirements in rule 657—8.3(155A). All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct personal supervision of an authorized nuclear pharmacist. An authorized 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 drug 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) *Pharmacy support persons.* A pharmacy support person shall register with the board pursuant to the registration requirements of 657—Chapter 5. Alternatively, a pharmacy support person may register with the board as a pharmacy technician pursuant to the registration and national certification requirements of 657—Chapter 3.

16.4(5) *Records required.* Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with rules of the board, the public health department, and the environmental protection commission.

16.4(6) *Compliance.* Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies, including those laws and regulations governing nonradioactive drugs. Nuclear pharmacies shall comply with all standards identified in United States Pharmacopeia General Chapter 825.

16.4(7) *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(8) *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(9) *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(10) *Radioactivity.* The amount of radioactivity for a radiopharmaceutical prepared by a nuclear pharmacy shall be determined by radiometric methods immediately prior to dispensing.

16.4(11) *Redistribution.* When a nuclear pharmacy distributes to another entity radioactive drugs that are FDA-approved, commercially manufactured drug products, the pharmacy shall not process the radioactive drugs in any manner or violate the product packaging.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 3525C**, IAB 12/20/17, effective 1/24/18; **ARC 5352C**, IAB 12/30/20, effective 2/3/21]

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. A reference including all pertinent Iowa laws, rules, and regulations that impact the pharmacy's practice;

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.

[**ARC 2196C**, IAB 10/14/15, effective 11/18/15]

657—16.6(155A) Minimum equipment requirements. Each nuclear pharmacy shall maintain the following equipment for use in the provision of radiopharmaceutical services:

1. Appropriate primary engineering control device to comply with rule 657—16.8(155A);
2. Dose calibrator;
3. Single-channel scintillation counter;
4. Microscope;
5. Incubator, or access to one;
6. Radiation survey meter;
7. Other equipment necessary for the radiopharmaceutical services provided as required by the board.

A pharmacy may request waiver from a provision of this rule pursuant to the procedures and requirements of 657—Chapter 34.

[**ARC 3525C**, IAB 12/20/17, effective 1/24/18; **ARC 5348C**, IAB 12/30/20, effective 2/3/21]

657—16.7(155A) Training and utilization of pharmacy support persons. Nuclear pharmacies utilizing pharmacy support persons shall develop, implement, and periodically review written policies and procedures for the training and utilization of pharmacy support persons. Pharmacy policies shall specify the frequency of review. Pharmacy support person training shall be documented and maintained by the pharmacy for the duration of employment. Such policies and procedures and documentation of pharmacy support person training shall be available for inspection by the board or an agent of the board.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

657—16.8(155A) Sterile radiopharmaceutical preparations and compounding. Sterile radiopharmaceutical preparations shall comply with federal laws and regulations for radiopharmaceuticals, including enforceable chapters of the United States Pharmacopeia (USP) and final guidance documents regarding sections of the Federal Food, Drug, and Cosmetic Act.

[**ARC 3525C**, IAB 12/20/17, effective 1/24/18]

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 DISTRIBUTOR LICENSES

657—17.1(155A) Purpose and scope. This chapter establishes the licensing requirements and standards applicable to a wholesale distributor of human prescription drugs as defined by Iowa Code section 155A.3 and the Drug Supply Chain Security Act. In the event the requirements in this chapter directly conflict with any federal law or regulation, the federal law or regulation shall supersede the requirements in this chapter.
[**ARC 4190C**, IAB 12/19/18, effective 1/23/19; **ARC 5008C**, IAB 3/25/20, effective 4/29/20]

657—17.2(155A) Definitions. In addition to the definitions found in Iowa Code section 155A.3, which are adopted for the purposes of this chapter, the following definitions shall apply:

"Drug Supply Chain Security Act" or *"DSCSA"* means the law enacted by Congress in November 2013 which establishes the minimum standards for ensuring a legitimate drug supply chain.

"Facility manager" means the individual responsible for managing the daily operations of the wholesale distribution facility.

"FDA" means the United States Food and Drug Administration.

"Returns processor" means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from a purchaser, manufacturer, or seller who purchased or received such product at wholesale, such that the product may be processed for credit to the purchaser, manufacturer, or seller, or disposed of for no further distribution.

"Wholesale distribution" means the distribution of a drug to a person other than a consumer or patient, or the receipt of a drug by a person other than a consumer or patient, but does not include transactions identified in Iowa Code section 155A.3 and DSCSA.

"Wholesale distributor" means a person, other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager, engaged in the wholesale distribution of a prescription drug.
[**ARC 4190C**, IAB 12/19/18, effective 1/23/19; **ARC 5008C**, IAB 3/25/20, effective 4/29/20]

657—17.3(155A) Wholesale distributor license. Every wholesale distributor that engages in wholesale distribution into, out of, or within this state must be licensed by the board before engaging in wholesale distribution. Where operations are conducted at more than one location by a single wholesale distributor, each such location shall be separately licensed. The applicant shall submit a completed application with a nonrefundable application fee of $750. A wholesale distributor that engages in wholesale distribution of controlled substances into, out of, or within this state shall also obtain a controlled substances Act registration pursuant to 657—Chapter 10.

17.3(1) *Application.* The applicant shall complete an application which requires demographic information about the wholesale distributor, ownership information, information about the wholesale distributor's registered agent located in Iowa, information about the wholesale distributor's licensure with other state and federal regulatory authorities, criminal and disciplinary history information, information regarding the facility manager, a detailed description of the services to be provided in this state, and other necessary information as determined by the board. An application for a wholesale distributor 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, including opening for business, within six months of receipt by the board of the required application(s). The following shall also be submitted by the applicant for the application to be considered complete:

a. Criminal history record check. Upon receipt of a licensure application, the board shall provide a fingerprint packet to the applicant's facility manager, who shall submit the completed fingerprint packet and a signed waiver form to facilitate a national criminal history background check of the facility manager. The cost of the evaluation of the fingerprint packet and the Iowa division of criminal investigation and the United States Federal Bureau of Investigation criminal history background checks will be assessed to the applicant.

b. Surety bond or equivalent security. The applicant shall file with the board a $100,000 surety bond or evidence that the wholesale distributor possesses the required bond in another state where the wholesale distribution facility does business. If a wholesale distributor's annual gross receipts from the previous tax year were $10 million or less, the wholesale distributor need only file a $25,000 surety bond. In lieu of a surety bond, the applicant may submit an irrevocable standby letter of credit in the amount of $100,000 or $25,000 as applicable. A government-owned wholesale distributor is exempt from the surety bond requirement.

c. Evidence of current drug distributor accreditation by the National Association of Boards of Pharmacy (NABP), the National Coalition for Drug Quality and Security (NCDQS), or another accreditation body approved by the board. This requirement does not apply to new applicants located in Iowa which must undergo an opening inspection by a board compliance officer or agent of the board prior to issuance of an initial license. Wholesale distributors located in Iowa shall provide evidence of drug distributor accreditation on or before license renewal.

d. Attestation by facility manager. The applicant shall submit attestation that the facility manager has been employed full-time for at least three years in a position related to prescription drug distribution; is actively involved in the daily operation of the wholesale distribution facility; maintains a functional understanding of federal and state laws, rules, and regulations pertaining to wholesale drug distribution; and has no felony convictions or convictions related to prescription drug distribution, including distribution of controlled substances.

17.3(2) *License renewal.* A wholesale drug license shall be renewed before January 1 of each year and may be renewed as early as November 1 prior to expiration. The wholesale distributor shall submit a completed application and nonrefundable application fee as required in this rule.

a. *Delinquent license grace period.* If a wholesale drug license has not been renewed or canceled prior to expiration, the license becomes delinquent on January 1. A wholesale distributor that submits a completed license renewal application, nonrefundable application fee, and nonrefundable late penalty fee of $750 postmarked or delivered to the board by January 31 shall not be subject to disciplinary action for continuing to provide services in this state in the month of January.

b. *Delinquent license reactivation beyond grace period.* If a wholesale drug license has not been renewed prior to the expiration of the one-month grace period identified in paragraph 17.3(2)*"a,"* the wholesale distributor may not operate or do business in Iowa. A wholesale distributor that continues to do business in Iowa without a current license may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.6(22). A wholesale distributor without a current license may apply for reactivation by submitting a license application for reactivation and a nonrefundable $2,000 reactivation fee. As part of the reactivation application, the wholesale distributor shall disclose the services, if any, that were provided in this state while the license was delinquent.

17.3(3) *License changes.* When a licensed wholesale distributor changes its name, ownership, facility manager, or location, a wholesale drug license application with a nonrefundable application fee as provided in subrule 17.3(1) shall be submitted to the board. A change of ownership occurs when the owner listed on the wholesale distributor's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the wholesale distributor's most recent application. A change of wholesale distributor location within Iowa, if the new location was not a licensed wholesale distributor immediately prior to the relocation, shall require an on-site inspection of the new location as provided in paragraph 17.3(1)*"c."*

a. *Locations in Iowa.* Applications for license changes shall be submitted to the board as far in advance as possible prior to the anticipated change.

b. *Locations outside of Iowa.* Applications for license changes shall be submitted to the board within ten days of the wholesale distributor's receipt of an updated license from the home state regulatory authority.

c. *License change application submission.* Applications for license changes shall be timely submitted pursuant to this subrule. A licensed wholesale distributor that has timely submitted a license change application and fee may continue to service Iowa customers while the license change is pending final approval. An applicant that has submitted an application for license changes after the required date

of submission pursuant to this subrule but within 30 days of the required date of submission shall be assessed a nonrefundable late penalty fee of $750 in addition to the license fee. An applicant that has submitted an application for license changes 31 days or later following the required date of submission pursuant to this subrule shall be assessed a nonrefundable reactivation fee of $2,000.

d. *Change in facility manager.* When a wholesale distributor has a change in facility manager, a new facility manager shall be identified pursuant to this paragraph. If a permanent facility manager is not currently the facility manager of a licensed facility, the facility manager shall submit to a criminal background check.

(1) If a permanent facility manager has been identified at the time of the vacancy, a wholesale distributor license application identifying the new permanent facility manager, along with the appropriate fee, shall be submitted to the board within ten days of the vacancy.

(2) If no permanent facility manager has been identified at the time of the vacancy, a temporary facility manager shall be identified and notice of such shall be submitted in writing to the board within ten days of the vacancy. A temporary facility manager shall not be required to submit a fingerprint packet and signed waiver to facilitate a national criminal history check unless the temporary facility manager subsequently is identified as the permanent facility manager. Within 90 days of the vacancy, a permanent facility manager shall be identified and a wholesale distributor license application identifying the permanent facility manager, along with the appropriate fee, shall be submitted to the board.

17.3(4) *License cancellation.* A licensee intending to discontinue wholesale distribution into, out of, or within this state shall notify the board in writing of its intent as far in advance as possible of the discontinuation of services and shall request that the license be administratively canceled. Such notification shall include the name and license number of the wholesale distributor, the anticipated date of discontinuation of service, and the identification of the wholesale distributor to which drugs and records will be transferred. To the extent possible to avoid unnecessary delays in obtaining product for patients, a wholesale distributor that intends to discontinue services in this state should provide advance notice to its customers of the date that the wholesale distributor intends to cease distribution in this state.

[**ARC 4190C**, IAB 12/19/18, effective 1/23/19; **ARC 5008C**, IAB 3/25/20, effective 4/29/20; **ARC 5351C**, IAB 12/30/20, effective 2/3/21]

657—17.4(155A) Grounds for denial. The board may deny a wholesale distributor license application, or refuse to renew a wholesale distributor license, for any of the following:

1. Any criminal convictions of the applicant or facility manager related to wholesale distribution;
2. Any felony convictions of the applicant;
3. Insufficient experience in the wholesale distribution business, including a lack of knowledge regarding the requirements of applicable federal and state laws or regulations;
4. The furnishing of false or fraudulent material;
5. Suspension, revocation, or other disciplinary action taken by the licensing authority of another state or federal agency against any license or registration currently or previously held by the applicant;
6. Noncompliance with licensing requirements under previously granted licenses, if any;
7. Noncompliance with the requirements to maintain or make available to the board, its agents, or to federal, state, or local law enforcement officials those records required to be maintained by wholesale distributors;
8. Conducting transactions with a person that is not properly licensed or registered; and
9. Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

[**ARC 4190C**, IAB 12/19/18, effective 1/23/19]

657—17.5 and **17.6** Reserved.

657—17.7(124,155A) Compliance with federal and state laws. A wholesale distributor is responsible for complying with all applicable federal and state laws, including those not specifically identified in this chapter.

17.7(1) A licensed wholesale distributor shall meet the requirements set forth in the Drug Supply Chain Security Act, including but not limited to:

a. 21 U.S.C. §360eee-1, relating to product tracing, product identifiers, authorized trading partners, suspect products, and illegitimate products;

b. 21 U.S.C. §360eee-2, relating to national standards for drug wholesale distributors; and

c. Any regulations promulgated thereunder.

17.7(2) A licensed wholesale distributor shall permit agents of the board to enter and inspect the facility for compliance with federal and state laws. A licensed wholesale distributor shall cooperate with other regulatory or law enforcement officials with jurisdiction over the facility.

[**ARC 4190C**, IAB 12/19/18, effective 1/23/19]

657—17.8(124,155A) Written policies and procedures. Wholesale distributors shall establish, maintain, and adhere to written policies and procedures that are in compliance with federal law 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. Wholesale distributors shall also include in their written policies and procedures the following:

17.8(1) *Recalls and market withdrawals.* A procedure to be followed for handling recalls and withdrawals of prescription drugs.

a. The procedure shall be adequate to deal with recalls and withdrawals due to:

(1) 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;

(2) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

b. The requirement of this subrule shall not apply to a returns processor.

17.8(2) *Emergency and disaster plan.* A procedure to ensure that wholesale distributors 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(3) *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. The requirement of this subrule shall not apply to a returns processor.

17.8(4) *Security and storage.* A procedure to ensure adequate security in accordance with rule 657—17.10(124,155A) and proper storage conditions in accordance with rule 657—17.11(155A). The requirement for proper storage conditions shall not apply to a returns processor.

17.8(5) *Drugs supplied to salesperson/representative.* If supplying drugs to wholesale distributor salespersons, a procedure directing that the security, storage, and record-keeping requirements contained in these rules shall be maintained by those salespersons.

17.8(6) *Personnel.* A procedure to ensure the wholesale distributor employs personnel with the education and experience appropriate to the responsibilities of the position held by the individual. Licensed wholesale distributors 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.

[**ARC 4190C**, IAB 12/19/18, effective 1/23/19]

657—17.9(155A) Facilities. All wholesale distribution facilities 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. Except for returns processors, 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.

[**ARC 4190C**, IAB 12/19/18, effective 1/23/19]

657—17.10(124,155A) Security.

17.10(1) *Secure from unauthorized entry.* All wholesale distribution facilities 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 wholesale distribution facilities shall be equipped with an alarm system to deter entry after hours.

17.10(3) *Security system.* All wholesale distribution 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.

[**ARC 4190C**, IAB 12/19/18, effective 1/23/19]

657—17.11(155A) Storage and handling. All prescription drugs shall be stored and shipped 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 the United States Pharmacopeia. Manual, electromechanical, or electronic temperature and humidity monitoring and recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs to prevent and detect excursions. Shipment of prescription drugs requiring refrigeration shall maintain temperature requirements in accordance with the manufacturer requirements or as described in the current edition of the United States Pharmacopeia. All excursions shall be evaluated to determine any adverse impact on the integrity of the drug. The requirements of this rule do not apply to nonsaleable returns handled by returns processors.

[**ARC 4190C**, IAB 12/19/18, effective 1/23/19]

657—17.12 to **17.16** Reserved.

657—17.17(155A) Reporting discipline and criminal convictions. No later than 30 days after the final action, a wholesale distributor shall provide to the board written notice, including an unredacted copy of the action or order, of any disciplinary or enforcement action imposed by any licensing or regulatory authority on any license or registration held by the wholesale distributor. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. No later than 30 days after conviction, a wholesale distributor shall provide to the board written notice, including an unredacted copy of the judgment of conviction or sentence, of any criminal conviction of the wholesale distributor, any owner of the wholesale distributor, or facility manager, if the conviction is related to prescription drug distribution. The term "criminal conviction" includes instances when the judgment of conviction or sentence is deferred.

[**ARC 4190C**, IAB 12/19/18, effective 1/23/19]

657—17.18(155A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a wholesale distributor license for any of the following:

1. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulation promulgated under the Act.

2. Any conviction of a crime related to the distribution of prescription drugs committed by the wholesale distributor, its owners, or the facility manager.

3. Refusing access to the wholesale distribution facility or records to an agent of the board for the purpose of conducting an inspection or investigation.

4. Failure to maintain registration pursuant to 657—Chapter 10 when distributing controlled substances into, out of, or within this state.

5. Any act of unethical or unprofessional conduct by an employee of the wholesale distributor.

6. Any violation of Iowa Code chapter 124, 126, 155A, or 205, or rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

[**ARC 4190C**, IAB 12/19/18, effective 1/23/19]

These rules are intended to implement Iowa Code sections 124.301 through 124.308, 126.3, 126.9 through 126.12, 155A.3, 155A.4, 155A.17, 155A.19, 155A.21, 155A.23, and 155A.40 and the federal Drug Supply Chain Security Act.

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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—39.13(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.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

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, which is available for inspection and copying by the board or its authorized agent, 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 and pharmacy support persons.

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 657—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, and such review shall not be delegated. 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, except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors, 657—subrule 8.19(8) for opioid antagonists, or 657—subrule 8.19(9) for expedited partner therapy.

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)";

(3) If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the prescription container label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological product)";

i. The initials or other unique identification of the pharmacist who performed drug use review, unless the identification of the pharmacist involved in each step of the prescription filling process is electronically documented and retrievable.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 3863C**, IAB 6/20/18, effective 7/25/18; **ARC 3985C**, IAB 8/29/18, effective 10/3/18; **ARC 4903C**, IAB 2/12/20, effective 3/18/20]

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 care facility, where Iowa law requires that drugs be administered to the patient by a health care professional.

[**ARC 3863C**, IAB 6/20/18, effective 7/25/18]

657—18.6 to **18.9** Reserved.

657—18.10(155A) Policy and procedures. Pursuant to rule 657—8.3(155A), 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 its authorized agent. The manual shall:

1. Outline the responsibilities of each of the pharmacies;
2. 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; and
3. Include, but not necessarily be limited to, policies and procedures for:

- Protecting the confidentiality and integrity of patient information;
- Protecting each patient's freedom of choice of pharmacy services;
- 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; and
- 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.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3863C**, IAB 6/20/18, effective 7/25/18]

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 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 initials or unique identification code of the pharmacist who performed drug use review. 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.

[**ARC 3863C**, IAB 6/20/18, effective 7/25/18]

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.

"FDA" means the United States Food and Drug Administration.

"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 that 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 services" includes, but is not limited to, nonproduct services provided by an Iowa-licensed pharmacist or a pharmacist practicing at an Iowa-licensed nonresident pharmacy, such as patient counseling and drug information, pharmaceutical care, and assessment of health risks.

"Registered pharmacist in charge" means the pharmacist in charge at the nonresident pharmacy who is registered with the board and is legally responsible for the operation of the nonresident pharmacy with respect to the provision of prescription drugs, devices, or pharmacy services to patients located in Iowa.
[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

657—19.2(155A) Nonresident pharmacy license. A nonresident pharmacy shall apply for and obtain, pursuant to provisions of rule 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. All requirements of rule 657—8.35(155A) regarding licensure are applicable to nonresident pharmacies unless otherwise provided in this rule. Any pharmacy that dispenses controlled substances to Iowa residents shall also register pursuant to 657—Chapter 10.

19.2(1) *Inspection requirements.* In lieu of the inspection requirement identified in 657—subrule 8.35(4), a nonresident pharmacy submitting any application for licensure, except when related to a change in location, shall submit with its application and fee an inspection report that satisfies the following requirements:

a. Less than two years have passed since the date of the inspection and the inspection report is the most recent inspection report available that satisfies the requirements of these rules.

b. The inspection occurred while the pharmacy was in operation. An inspection prior to the initial opening of the pharmacy shall not satisfy this requirement.

c. The inspection report addresses all aspects of the pharmacy's business that will be utilized in Iowa.

d. The inspection was performed by or on behalf of the home state licensing authority, if available.

19.2(2) *Qualified inspector.* If the home state licensing authority has not conducted an inspection satisfying the inspection requirements, the nonresident pharmacy shall submit an inspection report issued by one of the following:

a. The verified pharmacy program offered by the National Association of Boards of Pharmacy®.

b. Another qualified entity if the entity is preapproved by the board.

c. An authorized agent of the board. The board may recover from a nonresident pharmacy, prior to the issuance of a nonresident pharmacy license, the costs associated with conducting an inspection.

19.2(3) *Corrective action.* The nonresident pharmacy shall submit evidence of corrective action taken to satisfy any deficiency identified in the inspection report and of compliance with all legal directives of the home state licensing authority.

19.2(4) *Nonresident pharmacy license changes.* A nonresident pharmacy shall submit a completed application and fee pursuant to 657—subrule 8.35(6) except as provided in this rule.

a. *Name.* A change of the pharmacy name which is provided to patients shall require submission of a pharmacy license application and fee within ten days after issuance by the home state regulatory authority of a license bearing the new name.

b. *Location.* A change of pharmacy location shall require submission of a pharmacy license application, with the exception of the inspection requirements pursuant to subrule 19.2(1), and fee within ten days after issuance by the home state regulatory authority of a license bearing the new address.

c. *Pharmacist in charge.* A change in the pharmacist in charge shall require submission of a pharmacy license application and fee within ten days of the identification of a permanent pharmacist in charge pursuant to 657—subrule 8.35(6). If a temporary pharmacist in charge is identified, written notification shall be provided to the board pursuant to 657—paragraph 8.35(6)*"d."* The temporary pharmacist in charge shall not be required to be registered pursuant to rule 657—19.3(155A).

19.2(5) *Closing pharmacy or discontinuation of services.* If a nonresident pharmacy is closing, the pharmacy shall comply with the requirements in 657—subrule 8.35(7). If a nonresident pharmacy is discontinuing provision of pharmacy services to Iowa, but not closing, the pharmacy shall comply with the requirements in the introductory paragraph of 657—subrule 8.35(7) as it relates to transferring patient records to another Iowa-licensed pharmacy and 657—paragraphs 8.35(7)*"b"* and *"d."* The notice requirements of this rule shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster. The nonresident pharmacy shall return to the board the nonresident pharmacy license certificate and, if registered, the Iowa controlled substances Act registration certificate within ten days following the closure or discontinuation of service.

[**ARC 3237C**, IAB 8/2/17, effective 9/6/17; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—19.3(155A) Registered pharmacist in charge. The permanent pharmacist in charge of the nonresident pharmacy shall be designated as such on the nonresident pharmacy license application. Beginning January 1, 2018, the pharmacist in charge shall be registered with the board. The pharmacist in charge shall submit a completed application and a registration fee of $75. The registration shall expire on December 31 following the date of issuance of the registration. An initial registration issued between November 1 and December 31 shall not require renewal until the following calendar year.

19.3(1) *Registered pharmacist in charge application.* The pharmacist in charge of an Iowa-licensed nonresident pharmacy who is not currently actively licensed to practice pharmacy in Iowa shall be registered with the board. The pharmacist in charge shall submit to the board an application that includes the following information:

a. The pharmacist's name and contact information.

b. The pharmacist's license or registration number in the state in which the nonresident pharmacy is located.

c. The pharmacist's current place of employment.

d. Verification that the pharmacist's license in the state in which the nonresident pharmacy is located is current and in good standing.

e. Documentation that the applicant has successfully completed the most current educational training module approved by the board regarding the board's rules as they relate to nonresident pharmacy practice.

f. Criminal and disciplinary history information.

19.3(2) *Registration changes and voluntary cancellation.* A registered pharmacist in charge of a nonresident pharmacy shall notify the board in writing within ten days of any change of information included on the registration application, including the pharmacist's name, contact information, home state license or registration information or status, and place of employment. If a registered pharmacist in charge ceases to be the pharmacist in charge of an Iowa-licensed nonresident pharmacy, the pharmacist may voluntarily request that the registration be canceled and the pharmacist shall not be subject to the inactive registration and reactivation procedure as identified in paragraph 19.3(3)*"b."*

19.3(3) *Registration renewal.* The registration of a pharmacist in charge at a nonresident pharmacy shall be renewed or canceled prior to January 1 of each year. The pharmacist in charge shall submit a completed application and fee as required in this rule.

a. Delinquent registration grace period. If the registration of a pharmacist in charge has not been renewed or canceled prior to expiration, but the pharmacist is in the process of renewing the registration, the registration becomes delinquent on January 1. A pharmacist in charge who submits a completed registration renewal application, application fee, and late penalty fee of $75 postmarked or delivered to the board office by January 31 shall not be subject to disciplinary action for continuing to serve as pharmacist in charge without a current registration in the month of January.

b. Delinquent license reactivation beyond grace period. If the registration of a pharmacist in charge has not been renewed prior to the expiration of the one-month grace period identified in paragraph 19.3(3)*"a,"* the nonresident pharmacy may not continue to provide services to Iowa patients. A nonresident pharmacy that continues to provide services to Iowa patients without a currently registered pharmacist in charge may be subject to disciplinary sanctions. A pharmacist in charge without a current registration may apply for reactivation by submitting a registration application for reactivation and a $300 reactivation fee. As part of the reactivation application, the nonresident pharmacy shall disclose the services, if any, that were provided to Iowa patients while the registration of the pharmacist in charge was delinquent.

[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

657—19.4(124,155A) Applicability of board rules. A nonresident pharmacy shall comply with all requirements of this chapter, 657—Chapter 8, and any other board rules relating to the services that are provided by the pharmacy to patients in Iowa.

19.4(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 rule 657—6.1(155A) shall comply with all requirements of 657—Chapter 6.

b. A "hospital pharmacy" as described in rule 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(1) shall comply with all requirements of the limited use pharmacy practice.

d. An "outsourcing facility" as described in rule 657—41.2(155A) shall comply with all requirements of 657—Chapters 41 and 20.

19.4(2) *Controlled substances.* A nonresident pharmacy providing prescription drugs identified as controlled substances under Iowa Code chapter 124 shall register with the board and comply with all requirements of 657—Chapter 10.

19.4(3) *Compounding.* A nonresident pharmacy engaged in the compounding of drug products as defined in rule 657—20.2(124,126,155A) shall comply with all requirements of 657—Chapter 20.

19.4(4) *Long-term care services.* A nonresident pharmacy providing services to Iowa patients in a long-term care facility as defined in 657—Chapter 23 shall comply with all requirements of 657—Chapters 22 and 23.

19.4(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.

[**ARC 3237C**, IAB 8/2/17, effective 9/6/17; **ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—19.5 and **19.6** Reserved.

657—19.7(155A) Confidential data. Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have 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 rule 657—8.16(124,155A).

[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

657—19.8(124,155A) Storage and shipment of drugs and devices. Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure compliance with rules 657—8.7(155A) and 657—8.15(155A). 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 the date of delivery.
[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

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 rule 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 rule 657—8.21(155A), review the patient record and each prescription drug order before dispensing.

19.9(3) *Patient counseling.* Pursuant to rule 657—8.3(155A), each nonresident pharmacy shall have policies and procedures to ensure that Iowa patients receive appropriate counseling pursuant to the requirements of rule 657—6.14(155A).
[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

657—19.10(155A) Reporting discipline and criminal convictions. A nonresident pharmacy or registered pharmacist in charge shall provide notice to the board of any discipline imposed by any licensing authority on any license or registration held by the pharmacy or pharmacist in charge no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. A nonresident pharmacy or pharmacist in charge shall provide written notice to the board of any criminal conviction of the pharmacy, of any pharmacy owner, or of the pharmacist in charge that is related to prescription drugs or related to the operation of the pharmacy no later than 30 days after the conviction. The term "criminal conviction" includes instances when the judgment of conviction or sentence is deferred.
[**ARC 3237C**, IAB 8/2/17, effective 9/6/17]

657—19.11(155A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a nonresident pharmacy license or pharmacist in charge registration for any of the following:

1. Any violation of the Federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the FDA shall be conclusive evidence of a violation.
2. Any conviction of a crime related to prescription drugs or the practice of pharmacy committed by the nonresident pharmacy, pharmacist in charge, or individual owner, or if the pharmacy is an association, joint stock company, partnership, or corporation, by any managing officer.
3. Refusal of access to the pharmacy or pharmacy records to an agent of the board for the purpose of conducting an inspection or investigation.
4. Employing or continuing to employ a pharmacist in charge without a current and active registration pursuant to rule 657—19.3(155A).
5. Any violation of Iowa Code chapter 124, 124B, 126, 155A, or 205 or any rule of the board.

[**ARC 3237C**, IAB 8/2/17, effective 9/6/17; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 124.301, 124.306, 155A.13, 155A.13A, 155A.13C, 155A.19, and 155A.35.

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CHAPTER 20
COMPOUNDING PRACTICES

657—20.1(124,126,155A) Purpose and scope. The requirements of this chapter apply to compounded preparations that are dispensed, distributed, or administered to an ultimate user in the state of Iowa, regardless of the location of the pharmacy or outsourcing facility where the preparation was compounded. This chapter applies to compounded preparations intended for humans and animals. In addition to the requirements in this chapter, all pharmacies and outsourcing facilities engaged in compounding shall comply with all applicable federal laws and regulations governing compounding and all applicable state laws, rules and regulations governing the practice of pharmacy. In the event the requirements in this chapter directly conflict with any federal law or regulation, the federal law or regulation shall supersede the requirements in this chapter. The requirements of 657—Chapter 16 apply to the compounding of radiopharmaceuticals. The requirements of 657—Chapter 41 apply to outsourcing facilities.
[**ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—20.2(124,126,155A) Definitions. For purposes of this chapter, the following definitions apply:

"Anticipatory compounding" means the compounding of preparations in advance of the pharmacy's receipt of patient-specific prescriptions.

"Batch preparation compounding" means anticipatory compounding, compounding preparations intended for multiple disbursements, or compounding preparations in a multiple-dose container for administration to more than one patient.

"Beyond-use date" means the date after which a compounded preparation should not be used, determined from the date that the preparation is compounded.

"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.

"Compounding" means the combining, mixing, diluting, pooling, flavoring, or otherwise altering of a drug or bulk drug substance to create a drug. Compounding includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription products. Compounding does not include the use of a flavoring agent to flavor a drug pursuant to rule 657—20.13(124,126,155A), nor does it include mixing or reconstituting a drug according to the product's manufacturer label.

"FDA" means the Food and Drug Administration of the U.S. Department of Health and Human Services.

"Flavoring agent" means a therapeutically inert, nonallergenic substance consisting of inactive ingredients that is added to a drug to improve the drug's taste and palatability.

"Office use" means that a compounded product has been prepared and distributed to a practitioner for administration to a patient by the practitioner in the course of the practitioner's professional practice. A compounded product distributed to a practitioner for "office use" shall not require a patient-specific prescription and may not be further distributed to another practitioner or dispensed to a patient for self-administration.

"Outsourcing facility" or *"facility"* means any compounding facility that is registered as an outsourcing facility, as defined in 21 U.S.C. Section 353b, that distributes sterile compounded human drug products without a patient-specific prescription to an authorized agent or practitioner in this state.

"USP" means United States Pharmacopeia.
[**ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 2559C**, IAB 6/8/16, effective 7/13/16; **ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—20.3(124,126,155A) Nonsterile compounding. Iowa-licensed pharmacies that compound nonsterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 795 standards. Additional USP chapters incorporated by reference into USP Chapter 795 shall also be followed.
[**ARC 2194C**, IAB 10/14/15, effective 11/18/15]

657—20.4(124,126,155A) Sterile compounding. Iowa-licensed pharmacies that compound sterile preparations for ultimate users in the state of Iowa shall follow the current revision of USP Chapter 797 standards. Additional USP chapters incorporated by reference into USP Chapter 797 shall also be followed.
[**ARC 2194C**, IAB 10/14/15, effective 11/18/15]

657—20.5(126,155A) Delayed compliance. A pharmacy that cannot meet the requirements for full compliance with applicable USP chapters by the enforcement date established by USP shall not engage in compounding until the pharmacy is in full compliance with all requirements or the board has approved delayed compliance for the specific requirement or requirements requested. The board may establish a committee to grant or deny requests for delayed compliance. The board or committee may grant a request for delayed compliance only if the pharmacy can demonstrate progress toward full compliance and adequate protection of the public health, safety, and welfare during the period of delayed compliance. The board or committee may only grant a request for delayed compliance of specific requirements in applicable USP chapters for a maximum of 18 months.
[**ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 3238C**, IAB 8/2/17, effective 9/6/17; **ARC 4454C**, IAB 5/22/19, effective 6/26/19]

657—20.6(126,155A) Compounding standards for outsourcing facilities. An FDA-registered outsourcing facility shall be properly licensed in Iowa pursuant to 657—Chapter 41 and shall follow the FDA's current good manufacturing practices (cGMPs) for outsourcing facilities when compounding preparations for use in Iowa.
[**ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—20.7 and **20.8** Reserved.

657—20.9(124,155A) Prescriber/patient/pharmacist relationship. All compounded preparations shall be dispensed pursuant to a patient-specific prescription unless the compounded preparation is distributed pursuant to rule 657—20.15(124,126,155A) or 657—20.16(124,126,155A). A prescription for a compounded preparation shall be authorized by the prescriber for a specific patient. Prescriptions for all compounded preparations shall be maintained on file at the dispensing pharmacy.
[**ARC 2194C**, IAB 10/14/15, effective 11/18/15]

657—20.10(126,155A) Anticipatory compounding.

20.10(1) *Outsourcing facilities.* Outsourcing facilities are authorized to engage in anticipatory compounding. Outsourcing facilities are not required to obtain patient-specific prescriptions in order to distribute compounded preparations.

20.10(2) *Pharmacies.* Pharmacies may engage in anticipatory compounding only if the anticipatory compounding is based on a history of receiving valid prescriptions generated solely within an established prescriber/patient/pharmacist relationship, so long as each compounded preparation is dispensed pursuant to a patient-specific prescription.
[**ARC 2194C**, IAB 10/14/15, effective 11/18/15]

657—20.11(126,155A) Prohibition on resale of compounded preparations. The sale of compounded preparations to other pharmacies, prescribers, or entities, except as explicitly authorized by this chapter, is considered manufacturing.
[**ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—20.12(126,155A) Compounding copies of an approved drug. A pharmacy or outsourcing facility may only compound preparations that are essentially copies of approved drugs if the compounded preparation is changed to produce for an individual patient a clinically significant difference to meet a medical need as determined and authorized by the prescriber. A pharmacy or outsourcing facility may compound a preparation that is essentially a copy of an approved drug if the approved drug is identified as currently in shortage on the FDA drug shortages database published on the FDA website, www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

20.12(1) *Essentially a copy.* The board may consider the existence of the following factors as an indication that a compounded preparation is essentially a copy of an approved drug:

a. The compounded preparation has the same active pharmaceutical ingredient(s) as the commercially available drug product;

b. The active pharmaceutical ingredient(s) has the same, similar, or an easily substitutable dosage strength; and

c. The commercially available drug product can be used by the same route of administration as prescribed for the compounded preparation.

20.12(2) *Clinically significant difference.* The prescription for a compounded preparation that is essentially a copy of an approved drug shall clearly indicate the relevant change and the significant clinical difference produced for the patient. A prescription that identifies only a patient name and compounded preparation formulation is insufficient documentation for a pharmacy or outsourcing facility to rely upon to conclude that the prescriber made a determination regarding a clinically significant difference.

[**ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—20.13(124,126,155A) Use of flavoring agents. A flavoring agent may be added to a drug at the discretion of the pharmacist or upon the request of the prescriber, the patient, or the patient's agent. The pharmacist may add flavoring agents not to exceed 5 percent of the total volume of the drug to which the flavoring agents are added. The pharmacist shall label the flavored drug with a beyond-use date no greater than 14 days past the date the flavoring agent is added if the drug is required to be stored in a refrigerator. A different beyond-use date or alternate storage conditions may be indicated if such variation is supported by peer-reviewed medical literature. The pharmacist shall electronically or manually document that a flavoring agent was added to a drug, and such documentation shall be made available for inspection and copying upon the request of the board or an agent of the board.

[**ARC 2194C**, IAB 10/14/15, effective 11/18/15]

657—20.14 Reserved.

657—20.15(124,126,155A) Compounding for office use.

20.15(1) *Human compounded preparations.* Only an FDA-registered outsourcing facility properly licensed in Iowa pursuant to 657—Chapter 41 may distribute to a practitioner for office use human compounded preparations without a patient-specific prescription.

20.15(2) *Veterinary compounded preparations.* Veterinary compounded preparations may be sold to a practitioner for office use if the preparations are compounded by an Iowa-licensed pharmacy or outsourcing facility and sold directly to the practitioner by the pharmacy or outsourcing facility.

20.15(3) *Office use.* Compounded preparations distributed for office use pursuant to subrule 20.15(1) or 20.15(2) and in accordance with the labeling requirements of subrule 20.15(4) do not require a patient-specific prescription but do require that the compounded preparation be administered to a patient in the course of the practitioner's professional practice. Compounded preparations distributed for office use pursuant to this rule shall not be further distributed to other practitioners or dispensed to a patient for self-administration.

20.15(4) *Labeling.* Compounded preparations for office use, in addition to the labeling requirements specified in rule 657—20.19(124,126,155A), shall include on the prescription label the practitioner's name in place of the patient's name. The label shall state "For Office Use Only—Not for Resale." If the sterility or integrity of the compounded preparation cannot be maintained after the initial opening of the container, the label shall state "Single-Dose Only."

[**ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 2559C**, IAB 6/8/16, effective 7/13/16; **ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—20.16(124,126,155A) Compounding for hospital use. Compounded preparations distributed or dispensed to a hospital or hospital pharmacy pursuant to this rule shall be administered to an individual patient in the hospital.

20.16(1) *By an FDA-registered outsourcing facility.* Only an FDA-registered outsourcing facility properly licensed in Iowa pursuant to 657—Chapter 41 may distribute human compounded preparations to a hospital or hospital pharmacy in the absence of a patient-specific prescription. The compounded preparation shall be labeled in compliance with subrule 20.19(3).

20.16(2) *By a pharmacy that is not an FDA-registered outsourcing facility.* Human compounded preparations that are not compounded at an FDA-registered outsourcing facility may be dispensed to a hospital or hospital pharmacy by an Iowa-licensed pharmacy pursuant to a prescriber's authorization for administration to a specific patient. The compounded preparation shall be labeled in compliance with subrule 20.19(2).

[**ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—20.17 and **20.18** Reserved.

657—20.19(124,126,155A) Labeling. The label, or attached auxiliary labeling if necessary, affixed to the container of any compounded preparation dispensed or distributed into or within Iowa shall contain at least the information identified in one of the following subrules, as applicable.

20.19(1) *General pharmacy or outpatient dispensing.* The label shall meet the labeling requirements of 657—subrule 6.10(1) and shall include the following additional information:

a. The name and concentration of each active ingredient.

b. The date that the preparation was compounded.

c. The beyond-use date of the compounded preparation.

d. Special storage and handling instructions, if applicable.

e. The statement "COMPOUNDED PREPARATION" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

f. If the compounded preparation is sterile, the word "STERILE."

g. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

20.19(2) *Hospital pharmacy or inpatient administration.* The label shall meet the labeling requirements of 657—subrule 22.1(3) and shall include the following additional information:

a. The name and concentration of each active ingredient.

b. The date that the preparation was compounded.

c. The beyond-use date of the compounded preparation.

d. If the compounded preparation was prepared from batch preparation compounding, the batch identification or control number.

e. Special storage and handling instructions, if applicable.

20.19(3) *Outsourcing facility distribution or dispensing.* The label, or auxiliary labeling if necessary, shall include the following information:

a. The statement "THIS IS A COMPOUNDED DRUG" or a reasonable comparable alternative statement that prominently identifies the drug as a compounded preparation.

b. The name, address, and telephone number of the outsourcing facility that compounded the preparation.

c. The established name of the preparation.

d. The dosage form and strength.

e. The quantity of the preparation.

f. The date that the preparation was compounded.

g. The beyond-use date of the compounded preparation.

h. Storage and handling instructions.

i. The lot or batch identification or control number.

j. The national drug code number, if available.

k. The statement "Not for resale" and, if the preparation is dispensed or distributed other than pursuant to a patient-specific prescription, the statement "OFFICE USE ONLY."

l. The following additional information, which can be included on the labeling of a container (such as a plastic bag containing individual product syringes) from which individual units of the drug are removed for dispensing or for administration if there is not space on the label for such information:

(1) Directions for use including, as appropriate, dosage and administration;

(2) A list of the active and inactive ingredients, identified by established name and quantity or proportion of each ingredient;

(3) FDA contact information (www.fda.gov/medwatch and 1-800-FDA-1088 or successor website or telephone number) to facilitate adverse event reporting.

m. If the preparation is compounded pursuant to a prescription for a specific patient, the label shall also include the label requirements in 657—subrule 6.10(1).

n. If the preparation is compounded for office use, the label shall also include the label requirements in subrule 20.15(4).

[**ARC 2194C**, IAB 10/14/15, effective 11/18/15; **ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—20.20(126,155A) Labeling for batch preparation compounding. Compounded preparations resulting from batch preparation compounding shall be labeled with the following information until such time as the preparations are labeled pursuant to rule 657—20.19(124,126,155A) for distribution to hospitals or practitioners or for dispensing or administration to patients:

1. The date that the preparation was compounded.
2. Compounded preparation name or formula.
3. Dosage form.
4. Strength.
5. Quantity per container.
6. Unique internal batch identification or control number.
7. Beyond-use date.
8. Special storage and handling instructions, if applicable.

[**ARC 2194C**, IAB 10/14/15, effective 11/18/15]

657—20.21 and **20.22** Reserved.

657—20.23(124,126,155A) Records. All records required by this chapter shall be retained as original records of the pharmacy or outsourcing facility and shall be readily available for inspection and photocopying by agents of the board or other authorized authorities for at least two years following the date of the record. Records shall allow for the identification of all ingredients used in compounding, all personnel involved in compounding, and all personnel involved in reviewing compounded preparations. The pharmacy or outsourcing facility shall maintain records documenting the disbursements from each batch of a compounded preparation.

[**ARC 2194C**, IAB 10/14/15, effective 11/18/15]

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.13, 155A.13C, 155A.28, 155A.33, and 155A.35.

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CHAPTER 21
ELECTRONIC DATA AND AUTOMATED SYSTEMS IN PHARMACY PRACTICE

657—21.1(124,155A) Purpose and scope. The purpose of this chapter is to provide the minimum standards for the utilization of electronic data and automated systems in the practice of pharmacy and shall apply to all pharmacies located in Iowa.
[**ARC 3640C**, IAB 2/14/18, effective 3/21/18]

657—21.2(124,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Automated data processing system" means an application that is used for prescription, patient, drug, and prescriber information; installed on a pharmacy's computer or server; and controlled by the pharmacy.

"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. "AMDS" does not include electronic storage devices that do not have an electronic interface with one or more computers of the pharmacy.

"CSA" means the Iowa uniform controlled substances Act.

"CSA registration" means the registration issued by the board pursuant to the CSA that signifies the registrant's authorization to engage in registered activities with controlled substances.

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

"Electronically prepared prescription" means a prescription that is generated utilizing an electronic prescription application.

"Electronic device" means an electronic, mechanical, or other device which is used to intercept communications and includes but is not limited to network, file and print servers; desktop workstations; laptop computers; tablets; mini-computers; smart phones; and similar devices.

"Electronic prescription" means an electronically prepared prescription that is authorized and transmitted from the prescriber to the pharmacy by means of electronic transmission.

"Electronic prescription application" means software that is used to create electronic prescriptions and that is intended to be installed on a prescriber's computers and servers where access and records are controlled by the prescriber.

"Electronic signature" means a confidential personalized digital key, code, number, or other method used for secure electronic data transmissions which identifies a particular person as the source of the message, authenticates the signatory of the message, and indicates the person's approval of the information contained in the transmission.

"Electronic transmission" means the transmission of an electronic prescription, formatted as an electronic data file, from a prescriber's electronic prescription application to a pharmacy's computer, where the data file is imported into the pharmacy prescription application.

"Facsimile transmission" or *"fax transmission"* means the transmission of a digital image of a prescription from the prescriber or the prescriber's agent to the pharmacy. "Facsimile transmission" includes but is not limited to transmission of a written prescription between the prescriber's fax machine and the pharmacy's fax machine; transmission of an electronically prepared prescription from the prescriber's electronic prescription application to the pharmacy's fax machine or printer; or transmission of an electronically prepared prescription from the prescriber's fax machine to the pharmacy's fax machine, computer, or printer.

"Intermediary" means any technology system that receives and transmits an electronic prescription between the prescriber and the pharmacy.

"Pharmacist verification" or *"verified by a pharmacist"* means the accuracy of a prescription drug is verified by a pharmacist, pharmacist-intern, or technician in an approved technician product verification program.

"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, via facsimile, or in printed form.

"Readily retrievable" means that hard-copy or electronic records can be separated out from all other records within 72 hours of a request from the board or other authorized agent.

"Written prescription" means a prescription that is created on paper, a prescription that is electronically prepared and printed, or a prescription that is electronically prepared and transmitted from the prescriber's electronic device to a pharmacy via facsimile. A written prescription for a controlled substance shall be manually signed by the prescriber in compliance with federal and state laws, rules, and regulations.

[**ARC 3640C**, IAB 2/14/18, effective 3/21/18; **ARC 4580C**, IAB 7/31/19, effective 9/4/19; **ARC 5007C**, IAB 3/25/20, effective 4/29/20]

657—21.3(124,155A) System security and safeguards. To maintain the integrity and confidentiality of patient records and prescription drug orders, any system, computer, or electronic device 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. Authentication credentials shall be securely maintained by the individual to whom the credentials are issued and shall not be shared with or disclosed to any other individual. 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. An automated data processing system used for the receipt and processing of electronic transmissions from a prescriber's electronic prescription application shall comply with DEA requirements relating to electronic prescriptions and shall be certified compliant with DEA regulations.

[**ARC 3640C**, IAB 2/14/18, effective 3/21/18]

657—21.4 Reserved.

657—21.5(124,155A) Automated data processing systems. An automated data processing system may be used, subject to the requirements contained in this rule, for the storage and retrieval of prescription, patient, prescriber and drug data as well as data relating to the pharmacy staff utilization of the system.

21.5(1) *Electronic storage of hard-copy prescriptions.* A pharmacy that maintains an electronic copy of an original hard-copy prescription for a noncontrolled substance shall retain, in a readily retrievable format, the original hard-copy prescription as required in rule 657—6.8(155A) but shall be exempt from the requirement to record on the original hard-copy prescription the date and unique identification number of the prescription.

21.5(2) *Data retrievable and printable.* Any automated data processing system shall be capable of immediate retrieval (via computer monitor or hard-copy printout) of, at a minimum, any prescription, patient, prescriber, and drug data as well as data relating to pharmacy staff utilization of the system.

21.5(3) *Auxiliary procedure for system downtime.* A pharmacy utilizing an automated data processing system shall have a procedure that will maintain security and confidentiality of all data as well as ensure the legal dispensing of any prescription drug order in the event the system experiences downtime.

[**ARC 3640C**, IAB 2/14/18, effective 3/21/18]

657—21.6(124,155A) Electronic prescription applications. Beginning January 1, 2020, each prescription for a controlled substance shall be transmitted electronically to a pharmacy except as provided in rule 657—21.8(124,155A). Prior to January 1, 2020, a prescriber may, but shall not be required to, initiate and authorize a prescription drug order utilizing an electronic prescription application that has been determined to maintain security and confidentiality of patient information and records and, if prescribing controlled substances via an electronic prescribing system, certified compliant with DEA regulations for electronic prescribing of controlled substances. The prescription

drug order shall contain all information required by Iowa Code sections 155A.27 and 147.107(5). The receiving pharmacist shall be responsible for verifying the authenticity of an electronically prescribed prescription pursuant to rule 657—8.19(124,126,155A). A prescription that is electronically generated prior to January 1, 2020, or subject to exemption as provided in rule 657—21.8(124,155A), may be transmitted to a pharmacy via electronic or facsimile transmission or printed in hard-copy format for delivery to the pharmacy. A prescription that is transmitted by a prescriber's agent via electronic or facsimile transmission shall include the first and last names and title of the agent responsible for the transmission.

21.6(1) *Electronic transmission.* Beginning January 1, 2020, a prescription prepared pursuant to this rule shall be transmitted electronically to a pharmacy, unless exempt pursuant to rule 657—21.8(124,155A). A pharmacy shall be certified compliant with DEA regulations relating to electronic prescriptions prior to electronically receiving prescriptions for controlled substances. The electronic record shall serve as the original record and shall be maintained for two years from the date of last activity on the prescription. Any annotations shall be made and retained on the electronic record.

a. An electronically prepared and transmitted prescription that is printed following transmission shall be clearly labeled as a copy, not valid for dispensing.

b. The authenticity of a prescription transmitted via electronic transmission between a DEA-certified electronic prescription application and a DEA-certified electronic automated data processing system shall be deemed verified by virtue of the security processes included in those applications.

c. A pharmacy shall ensure that no intermediary has the ability to change the content of the prescription drug order or compromise its confidentiality during the transmission process. The electronic format of the prescription drug order may be changed by the intermediary to facilitate the transmission between electronic applications as long as the content of the prescription drug order remains unchanged.

d. In addition to the information requirements for a prescription, an electronically transmitted prescription shall identify the transmitter's telephone number for verbal confirmation, the telephone number where the prescriber can be contacted for timely consultation about patient care matters, 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.

e. If the transmission of an electronic prescription fails, the prescriber may print the prescription, manually sign the printed prescription, and deliver the prescription to the pharmacy via facsimile transmission in accordance with subrule 21.6(2).

21.6(2) *Printed (hard-copy) prescriptions.* A prescription electronically generated prior to January 1, 2020, or a prescription that is exempt from the electronic prescription mandate as provided in rule 657—21.8(124,155A), may be printed in hard-copy format for facsimile transmission or delivery to the pharmacy.

a. A prescription for a controlled substance shall include the prescriber's manual signature. Printed or hard-copy prescriptions for Schedule II controlled substances shall not be transmitted to a pharmacy via facsimile transmission, except as authorized in rule 657—21.7(124,155A).

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. Security features of the paper shall ensure that prescription information is not obscured or rendered illegible when transmitted via facsimile or when scanned into an electronic record system.

c. If the facsimile transmission of a printed prescription is a result of a failed electronic transmission, the facsimile shall indicate that it was originally transmitted to the named pharmacy, the date and time of the original electronic transmission, and the fact that the original transmission failed.

[**ARC 3640C**, IAB 2/14/18, effective 3/21/18; **ARC 4580C**, IAB 7/31/19, effective 9/4/19; **ARC 5350C**, IAB 12/30/20, effective 2/3/21]

657—21.7(124,155A) Facsimile transmission of a prescription. A pharmacist may dispense noncontrolled and controlled drugs, including Schedule II controlled substances only as provided in this rule, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the

practitioner's agent. The means of transmission via facsimile 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 shall serve as the original record, except as provided in subrule 21.7(1), shall be maintained for a minimum of two years from the date of the last activity on the prescription, and shall contain all information required by Iowa Code sections 155A.27 and 147.107(5), including the prescriber's signature. If the prescription is transmitted by an agent of the prescriber, the facsimile transmission shall include the first and last names and title of the agent responsible for the transmission. The pharmacist shall be responsible for verifying the authenticity of the prescription as to the source of the facsimile transmission.

21.7(1) *Schedule II controlled substances—emergency situations.* A pharmacist may, in an emergency situation as defined in 657—subrule 10.26(1), dispense a Schedule II controlled substance pursuant to a facsimile transmission to the pharmacy of a written, signed prescription from the prescriber or the prescriber's agent pursuant to the requirements of rule 657—10.26(124). The facsimile shall serve as the temporary written record required by 657—subrule 10.26(2).

21.7(2) *Schedule II controlled substances—compounded injectable.* A prescription for 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 prescriber or the prescriber's agent to a pharmacy via facsimile.

21.7(3) *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, as "long-term care facility" is defined in rule 657—23.2(155A), may be transmitted by the prescriber or the prescriber's agent to a pharmacy via facsimile. The prescription shall identify that the patient is a resident of a long-term care facility.

21.7(4) *Schedule II controlled substances—hospice patients.* A prescription for any Schedule II controlled substance for a patient in a hospice 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 prescriber or the prescriber's agent to the pharmacy. The prescription shall identify that the patient is a hospice patient.

[**ARC 3640C**, IAB 2/14/18, effective 3/21/18; **ARC 5350C**, IAB 12/30/20, effective 2/3/21]

657—21.8(124,155A) Electronic prescription mandate and exemptions. Beginning January 1, 2020, all prescriptions shall be transmitted electronically to a pharmacy except as provided in this rule.

21.8(1) *Prescriptions exempt.* Prescriptions which shall be exempt from electronic transmission include:

a. A prescription for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.

b. A prescription authorized by a licensed veterinarian.

c. A prescription for a device.

d. A prescription dispensed by a department of veterans affairs pharmacy.

e. A prescription requiring information that makes electronic transmission impractical, such as complicated or lengthy directions for use or attachments.

f. A prescription for a compounded preparation containing two or more components.

g. A prescription issued in response to a public health emergency in a situation where a non-patient-specific prescription would be permitted.

h. A prescription issued for an opioid antagonist pursuant to Iowa Code section 135.190 or a prescription issued for epinephrine pursuant to Iowa Code section 135.185.

i. A prescription issued during a temporary technical or electronic failure at the location of the prescriber or pharmacy, provided that a prescription issued pursuant to this paragraph shall indicate on the prescription that the prescriber or pharmacy is experiencing a temporary technical or electronic failure.

j. A prescription issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol.

k. A prescription issued in an emergency situation pursuant to federal law and regulation and rules of the board. An emergency situation may include, but is not limited to, the issuance of a prescription to meet the immediate care need of a patient after hours when a prescriber is unable to access electronic prescribing capabilities. Such prescription shall be limited to a quantity sufficient to meet the acute need of the patient with no authorized refills.

21.8(2) *Prescriber, medical group, institution, or pharmacy exemption.* A prescriber, medical group, institution, or pharmacy which has been granted an exemption to the electronic prescription mandate pursuant to rule 657—21.9(124,155A) shall be exempt from the electronic prescription mandate only for the duration of the approved exemption. Upon expiration of an approved exemption, the prescriber, medical group, institution, or pharmacy shall either comply with the electronic prescription mandate or timely petition the board for renewal of the exemption pursuant to rule 657—21.9(124,155A).
[**ARC 4580C**, IAB 7/31/19, effective 9/4/19]

657—21.9(124,155A) Exemption from electronic prescription mandate—petition. A prescriber, medical group, institution, or pharmacy that is unable to comply with the electronic prescription mandate in rule 657—21.8(124,155A) prior to January 1, 2020, may petition the board, on forms provided by the board, for an exemption from the requirements based upon economic hardship; technical limitations that the prescriber, medical group, institution, or pharmacy cannot control; or other exceptional circumstances. A prescriber, medical group, institution, or pharmacy seeking an exemption beginning January 1, 2020, shall submit a completed petition no later than October 1, 2019. A timely petition for renewal of a previously approved exemption shall be submitted at least 60 days in advance of the expiration of the previously approved exemption.

21.9(1) *Petition information.* A petition for exemption from the electronic prescription mandate shall include, but not be limited to, all of the following:

a. The name and address of the prescriber, medical group, institution, or pharmacy seeking the exemption. For medical groups and institutions, a list of the names, professional license numbers, and CSA registration numbers of all prescribers who would be covered by the exemption.

b. Whether the petitioner is seeking an exemption for controlled substance prescriptions, non-controlled substance prescriptions, or both.

c. The petitioner's current electronic prescribing capabilities.

d. The reason, such as economic hardship, technological limitations, or other exceptional circumstances, the petitioner is seeking exemption.

e. Supporting documentation to justify the reason for the exemption, including the following mandatory documentation:

(1) For economic hardship petitions, a copy of the petitioner's most recent tax return showing annual income and at least two quotes documenting the cost of implementing electronic prescribing.

(2) For technological limitation petitions, documentation showing the available Internet service providers, the speed and bandwidth available from each provider, and any data caps imposed by the Internet service provider, and documentation showing the minimum technological requirements from at least two electronic prescribing platform vendors.

f. Anticipated date of compliance with the electronic prescription mandate.

g. If the petition seeks renewal of a previously approved exemption, information relating to the petitioner's actions during the previous exemption period to work toward compliance with the electronic prescription mandate or an explanation as to why no progress has been made.

21.9(2) *Criteria for board consideration of a petition.* The board shall consider all information provided in a petition seeking exemption to the electronic prescription mandate and shall approve or deny a petition for exemption based on the following criteria:

a. If the reason for exemption is economic hardship, whether the cost of compliance with the electronic prescription mandate would exceed 5 percent of the petitioner's annual income as reported on the petitioner's most recent tax return.

b. If the reason for exemption is technological limitations, whether the Internet service providers available have the technological capabilities required by the electronic prescribing platform.

c. If the reason for exemption is other exceptional circumstances, examples of exceptional circumstances include, but are not limited to, whether the petitioner is a free or low-income clinic, whether the petitioner had a bankruptcy in the previous year, whether the petitioner intends to discontinue practice in Iowa prior to December 31, 2020, and whether the petitioner has a disability that limits the ability to utilize an electronic prescribing platform. All other exceptional circumstances will be evaluated on a case-by-case basis.

d. If the petition seeks renewal of a previous exemption to the electronic prescription mandate, the number of exemptions previously granted and updated information as it relates to the petitioner working toward compliance with the electronic prescription mandate or the explanation as to why no progress has been made.

21.9(3) *Duration of approved exemption.* The board may approve an exemption, or the renewal of an exemption, to the electronic prescription mandate for a specified period of time not to exceed one year from the date of approval.

[**ARC 4580C**, IAB 7/31/19, effective 9/4/19]

657—21.10(124,155A) Automated medication distribution system (AMDS). Any pharmacy that utilizes an AMDS shall comply with these rules in addition to all applicable federal and state laws, rules, and regulations.

21.10(1) *Policies and procedures.* Pursuant to the requirements regarding policies and procedures in 657—subrule 8.3(5), each pharmacy utilizing an AMDS shall have policies and procedures that address all aspects of the operation of the AMDS to include, at a minimum:

a. Access to drugs and patient information,

b. Pharmacy personnel training in the proper operation of the AMDS,

c. Methods to ensure accurate stocking of the AMDS pursuant to subrule 21.10(2),

d. Confidentiality of patient information,

e. Routine and preventative maintenance of the AMDS according to manufacturer recommendations,

f. Packaging and labeling of prescription drugs loaded into or dispensed from the AMDS that is in compliance with federal and state laws, rules, and regulations, and

g. Security and control of the prescription drugs maintained and utilized in the AMDS to include:

(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.

21.10(2) *Stocking the AMDS.* The pharmacy shall have adequate procedures in place to ensure the accurate stocking of drugs into an AMDS using barcode scanning technology. Only a pharmacy technician, pharmacist-intern, or pharmacist shall be allowed to participate in the stocking of the AMDS.

21.10(3) *Pharmacist verification of drugs dispensed from AMDS.*

a. When an AMDS only dispenses drugs that were prepackaged and verified by a pharmacist prior to being stocked in the AMDS and there was no further manipulation of the drug or package other than affixing a patient-specific label, such drugs shall not require additional pharmacist verification prior to administration or dispensing to the patient or authorized representative.

b. When a drug is stocked in an AMDS and undergoes further manipulation, such as counting and packaging, such drugs shall require pharmacist verification prior to dispensing to the patient. Such verification shall be documented.

21.10(4) *Placement of AMDS.*

a. An AMDS placed outside a pharmacist's direct supervision shall only dispense pharmacist-verified packages in compliance with paragraph 21.10(3)*"a."*

b. An AMDS that manipulates, including but not limited to counting, packaging, or labeling, prescription drugs for subsequent patient dispensing shall only be utilized in a pharmacy under the direct supervision of a pharmacist, except in an approved telepharmacy pursuant to 657—Chapter 13.
[**ARC 3640C**, IAB 2/14/18, effective 3/21/18]

657—21.11(124,155A) Pharmacist verification of controlled substance fills—daily printout or logbook. The individual pharmacist who makes use of the pharmacy prescription application shall provide documentation of the fact that the fill information entered into the pharmacy prescription application each time the pharmacist fills a prescription order for a controlled substance is correct. If the pharmacy prescription application provides a hard-copy printout of each day's controlled substance prescription order fill data, that printout shall be verified, dated, and signed by each individual pharmacist who filled 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 fill data shall be generated by and available at each pharmacy using a computerized pharmacy prescription application within 48 hours of the date on which the prescription 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 prescription information entered into the pharmacy prescription application that day has been reviewed by the pharmacist and is correct as shown. Pharmacist statements shall be signed in the manner previously described. The logbook or file shall be maintained at the pharmacy for a period of two years after the date of dispensing.
[**ARC 3640C**, IAB 2/14/18, effective 3/21/18]

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 147.107, 155A.27, 155A.33, 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 dose package" does not include a strip pack prepared utilizing an automated medication distribution system (AMDS). A strip pack is a patient med pak subject to the requirements of rule 657—22.5(126,155A).

"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)". If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological 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 657—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.

[**ARC 1309C**, IAB 2/5/14, effective 3/12/14; **ARC 3985C**, IAB 8/29/18, effective 10/3/18]

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. A patient med pak includes but is not limited to a strip pack prepared utilizing an automated medication distribution system (AMDS).

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 may 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 or returned to an automated medication distribution system (AMDS) component unless the drug was dispensed as a single dose and was not commingled with other patient medications in a single package or container.

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)". If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological 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.* The record of each patient med pak shall contain, at a minimum:

a. The name and address of the patient;

b. The unique identification number for each of the current prescription drug orders for each of the drug products contained therein;

c. A unique identification number for the patient med pak;

d. 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;

e. The date of preparation of the patient med pak and the beyond-use date that was assigned;

f. Any special labeling instructions; and

g. The name, unique identification, or initials of the responsible pharmacist.

This rule is intended to implement Iowa Code sections 126.10, 126.11, and 155A.28.

[**ARC 1309C**, IAB 2/5/14, effective 3/12/14; **ARC 2406C**, IAB 2/17/16, effective 3/23/16; **ARC 3985C**, IAB 8/29/18, effective 10/3/18]

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.* Contents of the emergency/first dose drug supply shall be provided by a primary 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. If the primary provider pharmacy does not supply or is unable to supply all drugs and products needed for the emergency care of facility patients, a second provider pharmacy may provide an emergency/first dose drug supply consisting only of drugs and products not stocked or available from the primary provider pharmacy including, but not limited to, parenteral or compounded drug products. The provider pharmacies 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 or pharmacists, 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 each 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 pharmacies and the facility to make drugs available, and emergency/first dose drug supplies 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 and is not intended to relieve any provider pharmacy from the provider pharmacy's responsibility to provide 24-hour services to facility patients; the intent is to ensure that a supply of drugs is available to each patient in case of urgent need. The drugs in emergency/first dose drug supplies are the responsibility of the respective provider 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. If the emergency/first dose drug supply contains a multidose package of a drug product that is removed from the supply for administration of one or more doses of the product to a patient and if following that administration the package contains one or more additional doses of the drug product and if the prescriber authorizes continuation of the drug product for that patient, the provider pharmacy shall complete either of the following processes.

a. Prepare and affix to the multidose package a label in compliance with rule 657—23.11(124,155A). The label shall be prepared and affixed to the package within 24 hours of administration of the emergency dose or doses.

b. Dispense, pursuant to a valid prescription order and in compliance with rule 657—23.11(124,155A), an appropriately labeled supply of the drug for the patient. The new prescription shall be delivered to the facility within 24 hours of administration of the emergency dose or doses.

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. Pursuant to rule 657—8.3(155A), established policies and procedures shall address notification, record keeping, and documentation procedures for use of the supply.

22.7(7) *Procedures.*

a. The pharmacy, in communication with the director of nursing of the facility and the medical director of the facility, or their respective designees, and as provided in rule 657—8.3(155A), shall have 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.

[**ARC 0749C**, IAB 5/29/13, effective 7/3/13; **ARC 1961C**, IAB 4/15/15, effective 5/20/15]

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 657—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 pharmacy, pursuant to rule 657—8.3(155A) and in coordination with the home health agency or hospice, shall have 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 pharmacist in charge and staff pharmacists shall share responsibility for 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.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15]

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CHAPTER 23
CARE FACILITY PHARMACY PRACTICE

657—23.1(155A) Purpose and scope. The purpose of this chapter is to identify the minimum standards for licensed pharmacies in this state providing pharmacy services to care facilities.
[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

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

"Care facility" or *"facility"* means:

1. A facility licensed by the Iowa department of inspections and appeals under Iowa Code chapter 135C or 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.

"Care facility pharmacy" or *"provider pharmacy"* means a pharmacy that provides pharmacy services to a care facility.

"Consultant pharmacist" in a care facility means an Iowa-licensed pharmacist who is responsible for developing, coordinating, and supervising pharmaceutical services in a care facility on a regularly scheduled basis.

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

"Medication order," as used in these rules, means an 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 care facility pharmacy or a provider pharmacy and who is responsible for supervising the accurate dispensing and proper delivery of drugs and devices to a 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.

"Unit dose dispensing system" means a drug distribution system utilizing unit dose packaging.
[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.3(124,155A) Freedom of choice. Pursuant to 657—subrule 8.11(2), no pharmacist or pharmacy shall participate in any agreement or plan that infringes on any resident's right to freedom of choice as described in rules of the department of inspections and appeals.
[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.4(124,155A) Responsibilities. The pharmacist in charge and staff pharmacists in any pharmacy providing pharmaceutical services to care facility patients shall share responsibility for:

1. Dispensing drugs pursuant to a medication order for an individual resident that are properly labeled and packaged in a manner consistent with the facility's established drug delivery system and in compliance with applicable board rules for the drug delivery system.
2. Affixing labels to each container of drugs for residents in care facilities, in compliance with 657—Chapter 22 or rule 657—6.10(126,155A), 657—23.13(124,155A), or 657—23.14(124,155A).
3. Maintaining records as required by law and maintaining accurate control over and accountability for all drugs and prescription devices.
4. Complying with a drug recall procedure, established pursuant to rule 657—8.3(155A), that protects the health and safety of residents.
5. Providing 24-hour emergency service either directly or by contract with another pharmacy.

6. Conducting prospective drug use review pursuant to rule 657—8.21(155A) and subrule 23.5(1).

7. Providing sufficient and accurate information to facility staff regarding the appropriate administration and use of all dispensed drugs and devices.

8. Communicating with the consultant pharmacist and the facility staff regarding concerns and resolution thereof.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.5(124,155A) Emergency drugs. A supply of emergency drugs may be provided by one or more pharmacies 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 emergency drug supplies, a care facility 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.

[**ARC 0749C**, IAB 5/29/13, effective 7/3/13; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.6(124,155A) Space, equipment, and supplies. Rescinded **ARC 3859C**, IAB 6/20/18, effective 7/25/18.

657—23.7(124,155A) Policies and procedures. Pursuant to rule 657—8.3(155A), each pharmacy shall have policies and procedures related to all aspects of the pharmacy's packaging and dispensing responsibilities to the residents of a 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.

5. An automatic stop order policy to ensure that drug orders are not continued inappropriately.

6. Methods to ensure that all discontinued, outdated, deteriorated, or improperly labeled drugs and all containers with worn, illegible or missing labels are disposed of so as to render them unusable and protected from unauthorized possession or use.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

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 or authorized pharmacist as part of a collaborative drug therapy management protocol pursuant to rule 657—39.13(155A).

23.9(1) *Requirements for noncontrolled substances.* New medication orders transmitted to the pharmacy for noncontrolled substances shall, at a minimum, contain resident name, drug name and strength, directions for use, date of order, and name of prescriber.

23.9(2) *Requirements for controlled substances.* New medication orders transmitted to the pharmacy for controlled substances, including Schedule II controlled substances, shall be in compliance with 657—Chapter 10, 657—Chapter 21, and federal regulations.

23.9(3) *Who may transmit medication orders.* An authorized prescriber or prescriber's agent may transmit to the pharmacy a medication order lawfully ordered by an authorized prescriber. An order transmitted by the prescriber's agent shall include the agent's first and last names and title. Specifically

for the transmission of a controlled substance prescription, a member of the care facility staff is an agent of the prescriber only if the prescriber maintains an office in the facility or there exists an agent agreement between the prescriber and the care facility staff member.
[**ARC 9912B**, IAB 12/14/11, effective 1/18/12; **ARC 2197C**, IAB 10/14/15, effective 11/18/15; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.10(124,155A) Stop orders. Rescinded **ARC 3859C**, IAB 6/20/18, effective 7/25/18.

657—23.11(124,155A) Drugs dispensed—general requirements.

23.11(1) *Labeling.* All prescription containers, other than those dispensed pursuant to 657—Chapter 22, rule 657—23.13(124,155A), or rule 657—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 pharmacist shall be responsible for affixing the correct label to the container. Care facility personnel shall not be directed by the pharmacy to affix such a label to the drug container.

b. Direction change labels that notify 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 657—23.5(124,155A) and 657—23.14(124,155A).

23.11(3) *Prescription containers.* All prescription containers utilized for dispensing drugs to a care facility shall meet minimum requirements as established by the United States Pharmacopoeia and 657—Chapter 22. When applicable, light-resistant packaging shall be used.

23.11(4) *Floor stock.* Prescription drugs, as defined by Iowa Code section 155A.3(38), shall not be floor-stocked in a 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.
[**ARC 2408C**, IAB 2/17/16, effective 3/23/16; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.12 Reserved.

657—23.13(124,155A) Labeling drugs under special circumstances.

23.13(1) *Drug products of insufficient size to accommodate pharmacy labeling.* Drug products, such as insulin, ophthalmics, otic preparations, and injectables, that are of insufficient size to accommodate a full pharmacy label 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 pharmacy may be stored in the locked medication area of a 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 and manufacturer labeling.

23.13(3) *Floor-stocked, nonprescription drug containers.* All nonprescription drugs for use within the facility shall be in appropriate containers and adequately labeled to identify, at a minimum, drug name and manufacturer, strength, lot number, and expiration date.

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 pharmacist 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 pharmacist shall be responsible for packaging and labeling discharge meds in compliance with this subrule.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.14(124,155A) Provision of drugs to a facility for immunization or screening programs. A pharmacy may provide drugs to be used in the care facility for a health immunization or ongoing screening program, such as influenza vaccine, tuberculin skin test, or hepatitis-B.

23.14(1) *Labeling.* The pharmacy label shall be affixed so as not to obscure the manufacturer's label and shall include the following information.

a. Identification of pharmacy;
b. Name of facility;
c. Name of biological or drug;
d. Route of administration when necessary for clarification;
e. Strength of biological or drug;
f. Auxiliary labels as needed;
g. Date dispensed.

23.14(2) *Influenza and pneumococcal vaccines.* A patient-specific medication order shall not be required prior to administration to an adult patient of influenza or pneumococcal vaccines pursuant to physician-approved facility policy and after the patient has been assessed for contraindications.

23.14(3) *Notification.* 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.

[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.15(124,155A) Return and reuse of drugs and devices. A pharmacy shall not accept from a patient or facility for reuse or resale any drug or device unless, in the professional judgment of the pharmacist, the integrity of the drug or device has not in any way been compromised. Under no circumstances shall a pharmacist accept from a patient or facility any controlled substances except for reuse by the same patient. Prescription drugs, excluding controlled substances, dispensed in a unit dose dispensing system pursuant to 657—Chapter 22 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 dispensing shall be accepted for return, exchanged, or resold by any pharmacist.

[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.16(124,155A) Destruction of outdated and improperly labeled drugs. Rescinded **ARC 3859C**, IAB 6/20/18, effective 7/25/18.

657—23.17(124,155A) Accountability of controlled substances. Use of Schedule II controlled substances shall be documented. 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. Documentation shall include at a minimum:

1. Name of drug;
2. Dose;
3. Name of ordering prescriber;

4. Name of resident;
5. Date and time of administration to resident;
6. Identification of individual administering;
7. 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.

[**ARC 3859C**, IAB 6/20/18, effective 7/25/18]

657—23.18(124,155A) Schedule II orders. Rescinded **ARC 3859C**, IAB 6/20/18, effective 7/25/18.

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 657—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 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 written or electronic 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).

[**ARC 9912B**, IAB 12/14/11, effective 1/18/12]

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

23.21(1) *Disposal in the facility.* A licensed health care professional (pharmacist, registered nurse, licensed practical nurse) may dispose of controlled substances in witness of one other responsible adult. The professional disposing of the drug shall prepare and maintain a readily retrievable record of the disposition which shall be clearly marked to indicate the disposition of resident drugs. The record shall include, at a minimum, the following:

a. Resident name and unique identification or number assigned by the dispensing pharmacy to the prescription;

b. The name, strength, and dosage form of the substance;

c. The quantity disposed of;

d. The date the substance is disposed of;

e. The signature or uniquely identifying initials or other unique identification of the professional and the witness;

f. The name and address of the dispensing pharmacy or the dispensing practitioner.

23.21(2) *Authorized collection program within a facility.* Pharmacies registered with DEA as authorized collectors may install and manage a collection receptacle in a care facility for the purpose of disposal of unwanted medications, including prescription drugs and controlled substances, pursuant to federal regulations.

[**ARC 0749C**, IAB 5/29/13, effective 7/3/13; **ARC 2408C**, IAB 2/17/16, effective 3/23/16; **ARC 3859C**, IAB 6/20/18, effective 7/25/18]

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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[Filed ARC 2197C (Notice ARC 2063C, IAB 7/22/15), IAB 10/14/15, effective 11/18/15]
[Filed ARC 2408C (Notice ARC 2285C, IAB 12/9/15), IAB 2/17/16, effective 3/23/16]
[Filed ARC 3345C (Notice ARC 3136C, IAB 6/21/17), IAB 9/27/17, effective 11/1/17]
[Filed ARC 3859C (Notice ARC 3511C, IAB 12/20/17), IAB 6/20/18, effective 7/25/18]

CHAPTER 24
PHARMACY INTERNET SITES

Rescinded **ARC 3346C**, IAB 9/27/17, effective 11/1/17

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 .

"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, a registration to practice as a pharmacy support person, 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.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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 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.
[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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 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 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, revocation, or denial of renewal.* 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—subrule 2.4(1) and shall pay all required examination fees pursuant to 657—subrule 2.5(3). A licensee whose registration to practice as a pharmacist-intern, as a pharmacy technician, or as a pharmacy support person or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete the appropriate 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.
[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 3346C**, IAB 9/27/17, effective 11/1/17; **ARC 4579C**, IAB 7/31/19, effective 9/4/19]

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.

[Filed 5/1/96, Notice 1/3/96—published 5/22/96, effective 6/26/96]
[Filed 2/22/99, Notice 10/21/98—published 3/10/99, effective 4/14/99]
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[Filed ARC 4579C (Notice ARC 4391C, IAB 4/10/19), IAB 7/31/19, effective 9/4/19]

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 of pharmacy 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:

IOWA BOARD OF PHARMACY

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 657—26.4(17A).
7. Original signature of petitioner and date signed.

[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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 Director, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, or via electronic mail to andrew.funk@iowa.gov.

[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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 (ARRC). Upon request by the petitioner, the board shall schedule a brief and informal meeting between the petitioner and the board, a member of the board, or a member of board staff 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 the petitioner and the ARRC of its action and the specific grounds for the denial, or grant the petition and notify the petitioner and the ARRC that it has initiated rule-making proceedings on the subject of the petition. The petitioner

and the ARRC 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 the petitioner and the ARRC.

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.

[**ARC 5348C**, IAB 12/30/20, effective 2/3/21]

These rules are intended to implement Iowa Code section 17A.7.

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[Filed ARC 5348C (Notice ARC 5113C, IAB 7/29/20), IAB 12/30/20, effective 2/3/21]

CHAPTER 27
DECLARATORY ORDERS

657—27.1(17A) Petition for declaratory order. Any person may file a petition with the board of pharmacy, 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 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

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.

[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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

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.
[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688.
[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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, 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—35.17(17A,272C).
[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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 Iowa Code section 17A.9(5), after receipt of a petition for a declaratory order, the board shall take action on the petition as required by Iowa Code section 17A.9(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).

[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

657—27.9(17A) Refusal to issue order.

27.9(1) The board shall not issue a declaratory order where prohibited by Iowa Code section 17A.9(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.

[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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.

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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, 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.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

657—28.2(17A) Definitions.

"Administrative rules review committee" or *"ARRC"* means a bipartisan standing committee composed of five senators and five representatives that meets on a regular basis for the purpose of selectively reviewing rules whether proposed or in effect.

"ARC" means the governor's administrative rules coordinator.

"ARC number" means the identification number assigned by the ARC to each rule making document.

"Iowa Administrative Bulletin" or *"IAB"* is the official biweekly publication that contains the text or texts of notices of intended action and of all adopted rules.

"Notice of Intended Action" means a published notice of the board's intent to adopt, amend, or rescind one or more rules pursuant to Iowa Code section 17A.4(1).
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

657—28.3(17A) Solicitation of comments before notice. In addition to seeking information by other methods, the board may, before publication of a Notice of Intended Action, solicit comments from the public on a subject matter of possible rule making by causing notice to be published in the Iowa Administrative Bulletin of the subject matter and indicating where, when, and how persons may comment.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

657—28.4(17A) Public rule-making docket. Proposed rule making is made available for inspection and comment by the public through the websites identified in this rule.

28.4(1) *Proposed rule making.* Each proposed rule making is published in the Iowa Administrative Bulletin and can be found on the state's administrative rules website at rules.iowa.gov. Each proposed rule making is identified by agency and by ARC number and shall include information on the opportunity to directly submit public comments, suggestions, and objections regarding the proposed rule making, including the deadline for submission of such comments.

28.4(2) *Rules tracker.* The progress and current status of any proposed rule making may be viewed at www.legis.iowa.gov/law/administrativerules/tracker.

28.4(3) *Board notification of proposed rule making.* Persons desiring to receive copies of future Notices of Intended Action may subscribe on the board's website at pharmacy.iowa.gov.

28.4(4) *Public participation—written comments.* For at least 20 days after publication of the Notice of Intended Action, persons may submit written comments 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, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or to the person designated in the Notice of Intended Action.

28.4(5) *Public participation—public hearings.* The board may, at any time, schedule a public hearing in accordance with rule 657—28.4(17A) on a proposed rule. The board shall schedule a public hearing 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 ARRC, a governmental subdivision, an agency, an association having not less than 25 members, or at least 25 persons. The request shall contain the following information:

a. A request by one or more individual persons shall include the printed name, signature, address, telephone number, and email address of each person.

b. A request by an association shall contain a statement that the association has at least 25 members and include the printed name, signature, address, telephone number, and email address of an officer or designee of the association.

c. A request by an agency or governmental subdivision shall contain the printed name, signature, address, telephone number, and email address of an official having authority to act on behalf of the entity.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

657—28.5(17A) Public hearing proceedings.

28.5(1) *Applicability.* This rule applies only to those public hearings in which an opportunity to make oral presentations is authorized or required by Iowa Code section 17A.4(1)*"b."*

28.5(2) *Scheduling and notice.* A public hearing 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 IAB. That notice shall also identify the proposed rule by ARC number and citation to the IAB.

28.5(3) *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.

28.5(4) *Conduct of hearing.* At a public hearing 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 hearing and indicate the general subject of their presentations. At the hearing, 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. Hearings shall be open to the public and shall be recorded by stenographic or electronic means.

a. At the beginning of the public hearing, 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 hearing. 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.

b. Persons making oral presentations are encouraged to avoid restating matters which have already been submitted in writing.

c. To facilitate the exchange of information, the presiding officer may, where time permits, open the floor to questions or general discussion.

d. The presiding officer shall have the authority to take any reasonable action necessary for the orderly conduct of the meeting.

e. Physical and documentary submissions presented by participants in the hearing shall be submitted to the presiding officer. Such submissions become the property of the board.

f. The hearing may be continued by the presiding officer to a later time without notice other than by announcement at the hearing.

g. Participants in a public hearing shall not be required to take an oath or to submit to cross-examination. However, the presiding officer in a hearing 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.

h. The presiding officer in a hearing may permit rebuttal statements and request the filing of written statements subsequent to the adjournment of the oral presentations.

28.5(5) *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(6) *Accessibility.* The board shall schedule public hearings in rooms accessible to and functional for persons with physical disabilities. Persons who have special requirements should contact the board, telephone (515)281-5944, in advance to arrange access or other needed services.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

657—28.6(17A) Regulatory analyses.

28.6(1) *Definition of small business.* A "small business" is defined in Iowa Code section 17A.4A(8)*"a."*

28.6(2) *Regulatory analysis—economic impact.* The board shall issue a regulatory analysis of a proposed board rule in response to a written request from the ARC or the ARRC. The regulatory analysis shall conform to the requirements of Iowa Code section 17A.4A.

28.6(3) *Regulatory analysis—business impact.* The board shall issue a regulatory analysis of a proposed board rule in response to a written request from one of the following. The regulatory analysis shall conform to the requirements of Iowa Code section 17A.4A.

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(4) *Time period for analysis.* Upon receipt of a timely request for a regulatory analysis, the board shall adhere to the time lines described in Iowa Code section 17A.4A.

28.6(5) *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 Iowa Code section 17A.4A.

28.6(6) *Contents of concise summary.* The contents of the concise summary shall conform to the requirements of Iowa Code section 17A.4A.

28.6(7) *Publication of a concise summary.* The board shall make available, to the maximum extent feasible, copies of the published summary in conformance with Iowa Code section 17A.4A.

28.6(8) *Jobs impact statement.* Pursuant to Iowa Code section 17A.4B, the board shall include in the preamble of each rule making a jobs impact statement, unless such statement is waived by the ARC. The board may seek and shall accept public comments and information from stakeholders relating to a jobs impact statement.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

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.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

657—28.8(17A) Time and manner of rule adoption.

28.8(1) *Time of adoption.* At least 35 days following publication of a Notice of Intended Action, the board may adopt a rule or terminate the rule making. Within 180 days after the date of publication of the notice or the deadline for public comments, whichever is later, the board shall adopt a rule or terminate the proceeding. Subsequent actions shall be published 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, jobs impact statement, 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.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

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) 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.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

657—28.10(17A) Exemptions from public rule-making procedures.

28.10(1) *Emergency-adopted rule.* 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, and with the prior approval of the ARRC and ARC, or if a statute so provides, 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) *Notice of emergency-adopted rule.* The board may, at any time, begin a standard rule-making proceeding for the adoption of a rule that is emergency-adopted without notice pursuant to subrule 28.10(1) and that is identical or similar to a rule it adopts in reliance upon subrule 28.10(1). After notice commenced pursuant to this subrule, the board may either readopt the rule it emergency-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.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

657—28.11(17A) Concise statement of reasons. 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 pursuant to Iowa Code section 17A.4(2). Requests for such a statement shall be in writing and be delivered to the Iowa Board of Pharmacy, 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.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

657—28.12(17A) Style and form. In preparing its rules, the board shall follow the uniform numbering system, form, and style prescribed by the administrative rules coordinator.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

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;

b. 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;

c. 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;

d. A copy of any regulatory analysis or fiscal impact statement;

e. A copy of the rule and any concise statement of reasons prepared for that rule;

f. All petitions for amendment of, or repeal or suspension of, the rule;

g. 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(6), and any board response to that objection;

h. A copy of any significant written criticism of the rule, including a summary of any petitions for waiver of the rule; and

i. 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 paragraph 28.13(2)*"g," "h,"* or *"i,"* for a period of not less than five years from the date of the written criticism.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

657—28.14(17A) Filing of rules. The board shall file each rule the board adopts with the office of the administrative rules coordinator. The filing shall be executed as soon after adoption of the rule as is practicable. In filing a rule, the board shall use the standard form prescribed by the administrative rules coordinator.
[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

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,"* 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.

[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

657—28.16(17A) Review by board of rules. Over each five-year period of time beginning July 1, 2012, the board shall conduct an ongoing and comprehensive review of all the board's rules pursuant to Iowa Code section 17A.7(2). The purpose of the review is to identify and eliminate all rules that are outdated, redundant, or inconsistent or incompatible with statute, other board rules, or rules of other agencies. When the board's five-year review of its rules is completed, the board shall summarize the results and provide the summary to the ARC and the ARRC.

[**ARC 3641C**, IAB 2/14/18, effective 3/21/18]

These rules are intended to implement Iowa Code sections 17A.1 through 17A.9A.

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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 except as authorized by these rules.
[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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. 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 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.
[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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, a board member must obtain prior written consent unless the sale is specifically allowed in rule 657—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.
[**ARC 3346C**, IAB 9/27/17, effective 11/1/17]

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
IOWA MONITORING PROGRAM FOR PHARMACY PROFESSIONALS

657—30.1(272C) Iowa monitoring program for pharmacy professionals committee. Pursuant to the authority of Iowa Code section 272C.3(1)*"k,"* the board establishes the committee for the Iowa monitoring program for pharmacy professionals. The purpose of the committee is to provide a program to support the evaluation and monitoring of licensees who are impaired as a result of alcohol or drug abuse, dependency, or addiction, or by any mental or physical disorder or disability, while protecting the health, safety and welfare of the public.
[**ARC 2834C**, IAB 12/7/16, effective 1/11/17]

657—30.2(272C) Definitions. For purposes of these rules, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Committee" means the Iowa monitoring program for pharmacy professionals committee.

"Contract" means the written document executed by an applicant or licensee and the committee after the committee receives a report from an approved treatment provider, which establishes the terms for participation in the program.

"Impairment" means an inability, or significant potential for inability, to practice with reasonable safety and skill as a result of a diagnosed substance use disorder or any diagnosed mental or physical health condition.

"Initial agreement" means the written document establishing the initial terms for participation in the program.

"Licensee" means a pharmacist licensed by the board, a pharmacist-intern registered with the board, or a pharmacy technician registered with the board.

"Participant" means an applicant or licensee who does any of the following: self-reports an impairment to the program, is referred to the program by the board, signs an initial agreement with the committee, or signs a contract with the committee.

"Program" means the Iowa monitoring program for pharmacy professionals.

"Self-report" means that an applicant or licensee provides written notification to the program that the applicant or licensee has been, is, or may be impaired. Information related to impairment or a potential impairment which is provided on a license application or renewal form may be considered a self-report.
[**ARC 2834C**, IAB 12/7/16, effective 1/11/17]

657—30.3(272C) Organization of the committee. The board shall appoint the members of the Iowa monitoring program for pharmacy professionals committee.

30.3(1) *Membership.* The membership of the committee includes, but is not limited to:

a. The executive director of the board or the director's designee from board staff;

b. One representative from the Drake University College of Pharmacy and Health Sciences;

c. One representative from the University of Iowa College of Pharmacy;

d. One board of pharmacy licensee who has maintained sobriety for a period of no less than two years following successful completion of a recovery program;

e. One health care professional with expertise in substance use disorders;

f. One health care professional with expertise in mental health; and

g. One public member.

30.3(2) *Officers.* At the last meeting of each calendar year, the committee shall elect a chairperson and a vice chairperson, each of whom will begin serving a one-year term on January 1.

a. The chairperson is responsible for offering guidance and direction to staff between regularly scheduled committee meetings, including guidance and direction concerning program descriptions, interim restrictions on practice, and negotiation and execution of initial agreements and contracts on behalf of the committee. The committee retains authority to review all interim decisions at its discretion.

b. The vice chairperson is responsible for providing guidance and direction to staff between regularly scheduled committee meetings if the chairperson is unavailable or unable to assist in a particular matter.

30.3(3) *Terms.* Committee members, except the executive director or designee, shall be appointed for three-year terms and shall serve for a maximum of three terms. Each term shall expire on December 31 of the third year of the term.
[**ARC 2834C**, IAB 12/7/16, effective 1/11/17]

657—30.4(272C) Eligibility.

30.4(1) *Self-report.* An applicant or a licensee shall self-report an impairment or potential impairment directly to the program.

30.4(2) *Board referral.* The board may refer an applicant or licensee to the program if a complaint or investigation reveals an impairment or potential impairment and the board determines that the applicant or licensee is an appropriate candidate for review by the committee. The board may refer a licensee to the program in a public disciplinary order or other public order.

30.4(3) *Review by the committee.* The committee will determine on a case-by-case basis whether an applicant or licensee who self-reports or is referred by the board is an appropriate candidate for participation in the program. Several factors may lead to the committee's determination that an applicant or licensee is ineligible to participate in the program, including but not limited to if the committee finds sufficient evidence that the applicant or licensee:

a. Diverted drugs for distribution to third parties or for personal profit;

b. Adulterated, misbranded, or otherwise tampered with drugs intended for a patient;

c. Provided inaccurate, misleading, or fraudulent information or failed to fully cooperate with the committee;

d. Participated in the program, or a similar program offered by another state, without success; or

e. Failed to sign an initial agreement or a contract when offered by the committee.

30.4(4) *Discretion.* Eligibility of a person to participate in the program is at the sole discretion of the committee. No person is entitled to participate in the program.

30.4(5) *Authority and jurisdiction.* Participation in the program does not divest the board of its authority or jurisdiction over the participant. A participant with an impairment or potential impairment may be eligible to participate in the program while being subject to investigation or discipline by the board for matters other than the alleged impairment.
[**ARC 2834C**, IAB 12/7/16, effective 1/11/17]

657—30.5(272C) Terms of participation. A participant shall agree to comply with the program terms of participation established in the initial agreement and the contract. Participants will be responsible for all expenses incurred to comply with the terms imposed by the program. Terms of participation specified in the contract shall include, but not be limited to:

30.5(1) *Duration.* The length of time a participant may participate in the program shall be determined by the committee in accordance with the following:

a. Participation in the program for participants impaired as a result of a substance use disorder is set at a minimum of three years. The committee may offer a contract with a shorter duration to a participant who can demonstrate successful participation in another state's monitoring program, who can document similar experience, or who, as a board referral, has successfully completed a portion of the monitoring period established in the board order.

b. Length of participation in the program for participants with impairments resulting from mental or physical conditions will vary depending upon the recommendations provided by health care providers and the determination of the committee following review of all relevant information.

30.5(2) *Requirements.* The committee shall establish terms of participation designed to meet the specific needs of a participant. The committee shall determine the type of recovery, rehabilitation, or maintenance program required to treat the participant's impairment. The contract shall provide a detailed description of the goals of the program, the requirements for successful participation, and the participant's obligations therein. The committee may establish terms of participation specific to a participant's impairment including, but not limited to, the following: treatment, aftercare, worksite monitoring, chemical screening, further evaluations, structured recovery meetings, therapy, and medication management.

30.5(3) *Practice restrictions.* The committee may impose restrictions on the license to practice as a term of the initial agreement or contract until such time as the committee receives a report from an approved evaluator, and the committee determines, based on all relevant information, that the participant is capable of practicing with reasonable skill and safety. As a condition of participation in the program, a licensee is required to agree to restricted practice in accordance with the terms specified in the initial agreement or contract. In the event the licensee refuses to agree to or comply with the practice restrictions, the committee shall refer the licensee to the board for appropriate action.

30.5(4) *Noncompliance.* Noncompliance is the failure to adhere to the terms of the initial agreement or contract. Participants shall promptly notify the committee of any instances of noncompliance, including relapse. Any instances of significant noncompliance shall be reported by the committee to the board. The report shall include a description of the noncompliance and the committee's recommendation as to whether the participant should remain in the program.

[**ARC 2834C**, IAB 12/7/16, effective 1/11/17]

657—30.6(272C) Confidentiality. Information in the possession of the board or the committee shall be subject to the confidentiality requirements of Iowa Code section 272C.6. Information about participants in the program shall not be disclosed except as provided in this rule.

30.6(1) The committee is authorized, pursuant to Iowa Code section 272C.6(4), to communicate information about a current or former program participant to the applicable regulatory authorities or licensee monitoring programs in the state of Iowa and in any jurisdiction of the United States or foreign nations in which the participant is currently licensed or in which the participant seeks licensure. Program participants must report their participation to the applicable monitoring program or licensing authority in any state in which the participant is currently licensed or in which the participant seeks licensure.

30.6(2) The committee is authorized to communicate information about a program participant to any person assisting in the participant's treatment, recovery, rehabilitation, monitoring, or maintenance for the duration of the contract.

30.6(3) The committee is authorized to communicate information about a program participant to the board in the event a participant does not comply with the terms of the contract as set forth in rule 657—30.5(272C). The committee may provide the board with a participant's program file in the event the participant does not comply with the terms of the contract and the committee refers the case to the board for the filing of formal disciplinary charges or other appropriate action. If the board initiates disciplinary action against a licensee for noncompliance with the terms of the contract, the board may include in the public disciplinary documents information about a licensee's participation in the program. The committee is also authorized to communicate information about a participant to the board in the event that the participant is under investigation by the board.

30.6(4) The committee is authorized to communicate information about a current or former program participant to the board if reliable information held by the committee reasonably indicates that a significant risk to the public exists. If the board initiates disciplinary action based upon this information, the board may include in the public disciplinary documents information about a licensee's participation if necessary to address impairment issues related to the violations which are the subject of the disciplinary action.

[**ARC 2834C**, IAB 12/7/16, effective 1/11/17]

657—30.7(28E) Authority for 28E agreements. The committee may enter into 28E agreements with other health professional licensing boards to evaluate, assist, and monitor impaired licensees from other health professions who self-report and to report to those professional licensing boards regarding the compliance of individual licensees. In the event of noncompliance, the licensee may be referred to the appropriate licensing board for appropriate disciplinary action.

[**ARC 2834C**, IAB 12/7/16, effective 1/11/17]

These rules are intended to implement Iowa Code section 272C.3(1)*"k."*

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[Filed ARC 0504C (Notice ARC 0351C, IAB 10/3/12), IAB 12/12/12, effective 1/16/13]
[Filed ARC 2834C (Notice ARC 2662C, IAB 8/3/16), IAB 12/7/16, effective 1/11/17]

CHAPTER 31
CRIMINAL CONVICTIONS

657—31.1(272C) Purpose and scope. The purpose of this chapter is to establish the process by which an individual's criminal history is utilized by the board in a determination of eligibility for licensure or registration and in licensing and registration decisions. This chapter applies to individuals who are seeking licensure or registration with the board and individuals who are seeking a licensure or registration eligibility determination from the board based on their prior criminal convictions.
[**ARC 5750C**, IAB 7/14/21, effective 8/18/21]

657—31.2(272C) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Complete criminal record" includes the complaint and judgment of conviction for each offense of which the applicant has been convicted, regardless of whether the offense is classified as a felony or a misdemeanor, and regardless of the jurisdiction in which the offense occurred.

"Conviction" means a finding, plea, or verdict of guilt made or returned in a criminal proceeding, even if the adjudication of guilt is deferred, withheld, or not entered. "Conviction" includes Alford pleas and pleas of nolo contendere.

"Disqualifying offense" means a conviction directly related to the duties and responsibilities of the practice of pharmacy. A conviction is directly related to the duties and responsibilities of the practice of pharmacy if either (1) the actions taken in furtherance of an offense are actions customarily performed within the scope of pharmacy practice, or (2) the circumstances under which an offense was committed are circumstances customary to licensed pharmacy personnel.

"License" means any license or registration issued by the board to an individual.
[**ARC 5750C**, IAB 7/14/21, effective 8/18/21]

657—31.3(272C) License application. Unless an applicant for licensure petitions the board for an eligibility determination pursuant to rule 657—31.4(272C), the applicant's convictions will be reviewed when the board receives a completed license application.

31.3(1) *Disclosure.* An applicant must disclose all convictions on a license application. Failure to disclose all convictions is grounds for license denial or disciplinary action following license issuance.

31.3(2) *Submission of criminal record and personal statement.* An applicant with one or more convictions shall submit the complete criminal record for each conviction and a personal statement regarding whether each conviction directly relates to the practice of pharmacy in order for the license application to be considered complete.

31.3(3) *Submission of evidence of rehabilitation.* An applicant must submit as part of the license application all evidence of rehabilitation that the applicant wishes to be considered by the board.

31.3(4) *Board authority.* The board may deny a license if the applicant has a disqualifying offense unless the applicant demonstrates by clear and convincing evidence that the applicant is rehabilitated pursuant to Iowa Code section 272C.15.

31.3(5) *Licensure requirements.* An applicant with one or more disqualifying offenses who has been found rehabilitated must still satisfy all other requirements for licensure.

31.3(6) *Nonrefundable fees.* Any application fees paid will not be refunded if the license is denied.
[**ARC 5750C**, IAB 7/14/21, effective 8/18/21]

657—31.4(272C) Eligibility determination.

31.4(1) An individual who has not yet submitted a completed license application may petition the board for a determination of whether one or more of the individual's convictions are disqualifying offenses that would render the individual ineligible for licensure. An individual with a conviction is not required to petition the board for an eligibility determination prior to applying for licensure.

31.4(2) To petition the board for an eligibility determination of whether one or more of the petitioner's convictions are disqualifying offenses, a petitioner shall submit all of the following:

a. A completed petition for eligibility determination form;

b. The complete criminal record for each of the petitioner's convictions;

c. A personal statement regarding whether each conviction directly relates to the duties and responsibilities of the practice of pharmacy and why the board should find the petitioner rehabilitated;

d. All evidence of rehabilitation that the petitioner wishes to be considered by the board; and

e. A nonrefundable fee of $25.

[**ARC 5750C**, IAB 7/14/21, effective 8/18/21]

657—31.5(272C) Appeal. A petitioner deemed ineligible for licensure or an applicant denied licensure due to a disqualifying offense may appeal the decision in the manner and time frame set forth in the board's written decision. A timely appeal will initiate a nondisciplinary contested case proceeding. The board's rules governing contested case proceedings will apply unless otherwise specified in these rules. If the petitioner or applicant fails to timely appeal, the board's written decision will become a final order.

31.5(1) *Presiding officer.* An administrative law judge will serve as the presiding officer of the nondisciplinary contested case proceeding, unless the board elects to serve as the presiding officer. When an administrative law judge serves as the presiding officer, the decision rendered shall be a proposed decision.

31.5(2) *Closed hearing.* The contested case hearing shall be closed to the public, and the board's review of a proposed decision shall occur in closed session.

31.5(3) *Burden of proof.* The office of the attorney general shall represent the board's initial ineligibility determination or license denial and shall have the burden of proof to establish that the convictions of the petitioner or applicant include at least one disqualifying offense. Upon satisfaction of this burden by a preponderance of the evidence by the office of the attorney general, the burden of proof shall shift to the petitioner or applicant to establish rehabilitation by clear and convincing evidence.

31.5(4) *Judicial review.* A petitioner or applicant must appeal an ineligibility determination or license denial in order to exhaust administrative remedies. A petitioner or applicant may only seek judicial review of an ineligibility determination or license denial after the issuance of a final order following a contested case proceeding. Judicial review of the final order following a contested case proceeding shall be in accordance with Iowa Code chapter 17A.

[**ARC 5750C**, IAB 7/14/21, effective 8/18/21]

657—31.6(272C) Future petitions or applications. If a final order determines a petitioner is ineligible, the petitioner may not submit a subsequent petition for eligibility determination or a license application prior to the date specified in the final order. If a final order denies a license application, the applicant may not submit a subsequent license application or a petition for eligibility determination prior to the date specified in the final order.

[**ARC 5750C**, IAB 7/14/21, effective 8/18/21]

These rules are intended to implement Iowa Code sections 272C.1(8) and 272C.15.

[Filed ARC 5750C (Notice ARC 5454C, IAB 2/24/21), IAB 7/14/21, effective 8/18/21]

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, a registration to practice as a pharmacy support person, 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.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10]

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 657—subrule 2.4(1) and shall pay all required examination fees pursuant to 657—subrule 2.5(3). A licensee whose registration to practice as a pharmacist-intern, as a pharmacy technician, or as a pharmacy support person or whose registration to handle controlled substances under Iowa Code chapter 124 has been revoked shall complete the appropriate 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.

[**ARC 8673B**, IAB 4/7/10, effective 6/1/10; **ARC 4579C**, IAB 7/31/19, effective 9/4/19]

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.

[Filed 11/24/08, Notice 10/8/08—published 12/17/08, effective 1/21/09]

[Filed ARC 8673B (Notice ARC 8380B, IAB 12/16/09), IAB 4/7/10, effective 6/1/10]
[Filed ARC 4579C (Notice ARC 4391C, IAB 4/10/19), IAB 7/31/19, effective 9/4/19]

CHAPTER 33
MILITARY SERVICE AND VETERAN RECIPROCITY

657—33.1(272C) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Military service" means honorably serving on federal active duty, state active duty, or national guard duty, as defined in Iowa Code section 29A.1; in the military services of other states, as provided in 10 U.S.C. Section 101(c); or in the organized reserves of the United States, as provided in 10 U.S.C. Section 10101.

"Military service applicant" means an individual requesting credit toward licensure or registration requirements for education, training, or service obtained or completed in military service.

"Veteran" means an individual who meets the definition of "veteran" in Iowa Code section 35.1(2).

[**ARC 1789C**, IAB 12/10/14, effective 1/14/15; **ARC 4582C**, IAB 7/31/19, effective 9/4/19; **ARC 5750C**, IAB 7/14/21, effective 8/18/21]

657—33.2(272C) Military education, training, and service credit. A military service applicant may apply for credit for verified military education, training, or service toward any experiential or educational requirement for pharmacist licensure, pharmacist-intern registration, or technician registration by submitting a military service credit application form to the board office. The board shall make available an application for military service credit.

33.2(1) *Military service credit application.* A military service credit application may be submitted with an application for licensure, examination, or registration or may be submitted prior to the submission of an application for licensure, examination, or registration. No fee is required with submission of a military service credit application.

33.2(2) *Credit identified.* The applicant shall identify the experiential or educational licensure or registration requirement to which the credit would be applied if granted. Credit shall not be applied to an examination requirement.

33.2(3) *Submission of verification documentation.* The applicant shall provide documents, military transcripts, a certified affidavit, or forms that verify completion of the relevant military education, training, or service, which may include, when applicable, the applicant's Certificate of Release or Discharge from Active Duty (DD Form 214) or Verification of Military Experience and Training (VMET) (DD Form 2586).

33.2(4) *Credit determination.* Upon receipt of a completed military service credit application, the board shall promptly determine whether the verified military education, training, or service will satisfy all or any part of the identified experiential or educational qualifications for licensure or registration.

33.2(5) *Granting of credit.* The board shall grant credit requested in the application in whole or in part if the board determines that the verified military education, training, or service satisfies all or part of the experiential or educational qualifications for licensure or registration.

33.2(6) *Notification of credit determination.* The board shall inform the military service applicant in writing of the credit, if any, given toward an experiential or educational qualification for licensure or registration or explain why no credit was granted. The applicant may request reconsideration of the board's determination upon submission of additional documentation or information.

33.2(7) *Consideration of applications.* The board shall grant or deny the military service credit application prior to ruling on the application for licensure, examination, or registration. The applicant shall not be required to submit any fees in connection with the license or registration application until the board issues a determination on the military service credit application. If the board does not grant the military service credit application, the applicant may withdraw any license or registration application and application fee, if submitted, or the applicant may request that the application be placed in pending status. The withdrawal of a license or registration application and fee shall not preclude subsequent applications supported by additional documentation or information.

[**ARC 1789C**, IAB 12/10/14, effective 1/14/15; **ARC 5750C**, IAB 7/14/21, effective 8/18/21]

657—33.3(272C) Veteran licensure or registration. A veteran with an unrestricted pharmacist license in another jurisdiction may apply for pharmacist licensure in Iowa by license transfer pursuant to rule

657—2.9(147,155A) and this chapter. A veteran must pass any required examinations to be eligible for pharmacist licensure by license transfer. A veteran may submit an application for pharmacist-intern registration pursuant to 657—Chapter 4 and this chapter. A veteran may submit an application for technician registration pursuant to 657—Chapter 3 and this chapter. A veteran may submit an application for pharmacy support person registration pursuant to 657—Chapter 5 and this chapter.

33.3(1) *Priority application status.* A fully completed application for licensure or registration submitted by a veteran or spouse under this chapter shall be given priority status and shall be expedited.

33.3(2) *Application requirements.* Such an application shall contain all of the information required of all applicants for licensure or registration who hold unrestricted licenses or registrations in other jurisdictions and who are applying for licensure or registration, including, but not limited to, completion of all required forms, payment of applicable fees, disclosure of criminal or disciplinary history, and, if applicable, a criminal history background check. In addition, the applicant shall provide such documentation as is reasonably needed to verify the applicant's status as a veteran under Iowa Code section 35.1(2).

33.3(3) *Equivalency determination.* Upon receipt of a fully completed application for licensure or registration, the board shall promptly determine if the requirements for licensure or registration of the jurisdiction where the veteran is licensed or registered are substantially equivalent to the requirements for licensure or registration in Iowa. The board may consider the following factors in determining substantial equivalence: scope of practice, education and coursework, degree requirements, and postgraduate experiences.

33.3(4) *Licensure or registration approval.* The board shall promptly grant a license or registration, as appropriate, to the veteran if the applicant is licensed or registered in another jurisdiction whose licensure or registration requirements are substantially equivalent to those required in Iowa, unless the applicant is ineligible for licensure or registration based on other grounds, for example, the applicant's disciplinary or criminal background.

33.3(5) *Notification of additional requirements and provisional licensure or registration.* If the board determines that the veteran is licensed or registered in another jurisdiction whose licensure or registration requirements are not substantially equivalent to those required in Iowa, the board shall promptly inform the applicant of the additional experience, education, or examinations required for licensure or registration in Iowa. Unless the applicant is ineligible for licensure or registration based on other grounds, such as disciplinary or criminal background, the following shall apply:

a. If the applicant has not passed the required examination(s) for licensure or registration, the applicant may request that the application be placed in pending status. The board may issue a provisional 90-day license in order for a pharmacist who has applied for license transfer pursuant to rule 657—2.9(147,155A) to take and pass the multistate pharmacy jurisprudence examination (MPJE), Iowa Edition.

b. If additional experience or education is required in order for the applicant's qualifications to be considered substantially equivalent, the applicant may request that the board issue a provisional license or registration for a specified period of time upon such conditions as the board deems reasonably necessary to protect the health, welfare, and safety of the public unless the board determines that the deficiency is of a character that the public health, welfare, or safety will be adversely affected if a provisional license or registration is granted.

c. If a request for a provisional license or registration is denied, the board shall issue an order fully explaining the decision and shall inform the applicant of the steps the applicant may take in order to receive a provisional license or registration.

d. If a provisional license or registration is issued, the application for full licensure or registration shall be placed in pending status until the necessary experience or education has been successfully completed or the provisional license or registration expires, whichever occurs first. The board may extend a provisional license or registration on a case-by-case basis for good cause.

[**ARC 1789C**, IAB 12/10/14, effective 1/14/15; **ARC 4582C**, IAB 7/31/19, effective 9/4/19; **ARC 5750C**, IAB 7/14/21, effective 8/18/21]

657—33.4(272C) Request for contested case. A military service applicant or a veteran who is aggrieved by the board's decision to deny all or part of the military service credit application, a request for a license transfer, a request for a registration, or a request for provisional license or registration, or is aggrieved by the terms under which a provisional license or registration will be granted, may request a contested case (administrative hearing) and may participate in a contested case by telephone. A request for a contested case shall be made within 30 days of issuance of the board's decision pursuant to 657—subrule 35.30(1). There shall be no fees or costs assessed against the military service applicant or veteran in connection with a contested case conducted pursuant to this chapter.

[**ARC 1789C**, IAB 12/10/14, effective 1/14/15; **ARC 4582C**, IAB 7/31/19, effective 9/4/19; **ARC 5750C**, IAB 7/14/21, effective 8/18/21]

These rules are intended to implement Iowa Code sections 272C.4(11) and 272C.4(12).

[Filed ARC 1789C (Notice ARC 1641C, IAB 10/1/14), IAB 12/10/14, effective 1/14/15]

[Filed ARC 4582C (Notice ARC 4483C, IAB 6/5/19), IAB 7/31/19, effective 9/4/19]

[Filed ARC 5750C (Notice ARC 5454C, IAB 2/24/21), IAB 7/14/21, effective 8/18/21]

CHAPTER 34
WAIVERS

657—34.1(17A) Definition. For purposes of this chapter, a "waiver" 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 "person" shall include both a person and a business.
[**ARC 5348C**, IAB 12/30/20, effective 2/3/21]

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 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.
[**ARC 3347C**, IAB 9/27/17, effective 11/1/17]

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. In response to a petition for waiver, 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.

[**ARC 3347C**, IAB 9/27/17, effective 11/1/17; **ARC 5348C**, IAB 12/30/20, effective 2/3/21]

657—34.5(17A,124,126,147,155A,205,272C) Filing of petition. A petition for 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 conjunction with the application for the license, registration, or permit in question.

34.5(2) *Contested cases.* If the petition relates to a procedural rule governing a pending contested case, the petition shall be filed in the contested case proceeding, using the caption of the contested case. A petition cannot be submitted to waive a substantive rule the respondent has been charged with violating in a pending 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 director.
[**ARC 3347C**, IAB 9/27/17, effective 11/1/17]

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 657—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. Any information known to the petitioner regarding the board's treatment of similar cases.

6. 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.

7. The name, address, and telephone number of any person who would be adversely affected by the granting of a petition for waiver.

8. The name, address, and telephone number of any person with knowledge of facts relevant to the proposed waiver.

[**ARC 3347C**, IAB 9/27/17, effective 11/1/17]

657—34.7(17A) Additional information and providing notice. 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. The board may provide notice of a petition for waiver to any person who might be affected by the waiver. The board shall provide public notice of any petitions for waiver by including any petitions for waiver on the agenda of the board meeting during which the petition for waiver will be discussed.

[**ARC 3347C**, IAB 9/27/17, effective 11/1/17]

657—34.8(17A) Notice. Rescinded **ARC 3347C**, IAB 9/27/17, effective 11/1/17.

657—34.9(17A) Hearing procedures. Rescinded **ARC 3347C**, IAB 9/27/17, effective 11/1/17.

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) *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(5) *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.

[**ARC 3347C**, IAB 9/27/17, effective 11/1/17]

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) Submission of waiver information. Within 60 days of granting or denying a waiver, the board shall make a submission on the Internet site established pursuant to Iowa Code section 17A.9A for the submission of waiver information. The submission shall identify 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 submission shall include a general summary of the reasons justifying the board's actions on waiver requests. If practicable, the submission shall detail the extent to which the granting of a waiver has established a precedent for additional waivers and the extent to which the granting of a waiver has affected the general applicability of the rule itself.
[**ARC 5348C**, IAB 12/30/20, effective 2/3/21]

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 conducted by the board of pharmacy.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.2(17A,272C) Definitions. Except where otherwise specifically defined by law:

"Board" means the Iowa board of pharmacy.

"Contested case" means a proceeding defined by Iowa Code section 17A.2(5), including but not limited to licensee disciplinary proceedings, license denial proceedings, and license reinstatement proceedings.

"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.

"License" means any license, registration, or permit issued by the board, regardless of whether the license, registration, or permit is active.

"Licensee" means any person or entity possessing a license, registration, or permit issued by the board, regardless of whether the license, registration, or permit is active.

"Party" means the state of Iowa, as represented by the office of the attorney general, and respondent or applicant.

"Probable cause" means a reasonable ground for belief in the existence of facts warranting the specified proceeding.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.3(17A) Time requirements.

35.3(1) *Computation.* Time shall be computed as provided in Iowa Code section 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.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.4(17A) Applicability of Iowa Rules of Civil Procedure. Except as expressly provided in Iowa Code chapter 17A and these rules, the Iowa Rules of Civil Procedure do not apply to contested case proceedings. However, upon application by a party, the board may permit the use of procedures provided for in the Iowa Rules of Civil Procedure unless doing so would unreasonably complicate the proceedings or impose an undue hardship on a party.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.5(17A,272C) Combined statement of charges and settlement agreement. Upon a determination by the board that probable cause exists to take public disciplinary action, the board and the licensee may enter into a combined statement of charges and settlement agreement.

35.5(1) No licensee is entitled to be offered a combined statement of charges and settlement agreement.

35.5(2) Entering into a combined statement of charges and settlement agreement is completely voluntary.

35.5(3) The combined statement of charges and settlement agreement shall include a brief statement of the charges, the circumstances that led to the charges, and the terms of settlement.

35.5(4) A combined statement of charges and settlement agreement shall constitute the commencement and resolution of a contested case proceeding. By entering into a combined statement of charges and settlement agreement, the licensee waives the right to a contested case hearing on the matter.

35.5(5) A combined statement of charges and settlement agreement is a permanent public record open for inspection under Iowa Code chapter 22.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.6(17A,124B,126,147,155A,205,272C) Notice of hearing.

35.6(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 restricted mail, return receipt requested; or

c. Signed acknowledgment accepting service; or

d. When service cannot be accomplished using the above methods:

(1) An affidavit shall be prepared outlining the measures taken to attempt service; and

(2) Notice of hearing shall be published once each week for three consecutive weeks in a newspaper of general circulation, published or circulated in the county of last-known residence of the respondent. The first notice of hearing shall be published at least 30 days prior to the scheduled hearing.

35.6(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;

e. Identification of all parties, including the name, address and telephone number of the assistant attorney general representing the state;

f. Reference to the procedural rules governing conduct of the contested case proceeding;

g. Reference to the procedural rules governing settlement;

h. Identification of the presiding officer;

i. Notification of the time period in which a party may request, pursuant to Iowa Code section 17A.11 and rule 657—35.10(17A,272C), that the presiding officer be an administrative law judge;

j. Notification of the time period in which the respondent may file an answer; and

k. Notification of the respondent's right to request a closed hearing, if applicable.

35.6(3) *Public record.* A notice of hearing is a permanent public record open for inspection under Iowa Code chapter 22.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.7(17A,272C) Statement of charges. In the event the board finds there is probable cause for taking public disciplinary action against a licensee, the board shall file a statement of charges. The statement of charges shall be incorporated within the notice of hearing. The statement of charges shall set forth the acts or omissions with which the respondent is charged, including the statute(s) and rule(s) which are alleged to have been violated, and shall be in sufficient detail to enable the preparation of the respondent's defense. Every statement of charges prepared by the board shall be reviewed by the office of the attorney general before it is filed. A statement of charges is a permanent public record open for inspection under Iowa Code chapter 22.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.8(13,272C) Legal representation. Following the issuance of a notice of hearing, the office of the attorney general shall be responsible for the legal representation of the public interest in the contested case. The assistant attorney general assigned to prosecute a contested case before the board shall not represent the board in that case but shall represent the public interest.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.9(17A,272C) Presiding officer in a disciplinary contested case. The presiding officer in a disciplinary contested case shall be the board. When acting as presiding officer, the board may request that an administrative law judge perform certain functions as an aid to the board, such as ruling on

prehearing motions, conducting the prehearing conference, ruling on evidentiary objections at hearing, assisting in deliberations, and drafting the written decision for review by the board.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.10(17A,272C) Presiding officer for nondisciplinary hearings.

35.10(1) *Request for administrative law judge.* Any party in a nondisciplinary contested case who wishes to request that the presiding officer assigned to render a proposed decision be an administrative law judge employed by the department of inspections and appeals must file a request within 20 days after service of a notice of hearing.

35.10(2) *Grounds for denial.* The board may deny the request only upon a finding that one or more of the following apply:

a. There is a compelling need to expedite issuance of a final decision in order to protect the public health, safety, or welfare.

b. An administrative law judge is unavailable to hear the case within a reasonable time.

c. The case involves significant policy issues of first impression that are inextricably intertwined with the factual issues presented.

d. The demeanor of the witnesses is likely to be dispositive in resolving the disputed factual issues.

e. Funds are unavailable to pay the costs of an administrative law judge and an interagency appeal.

f. The request was not timely filed.

g. The request is not consistent with a specified statute.

35.10(3) *Written ruling.* The board shall issue a written ruling specifying the grounds for its decision within 20 days after a request for an administrative law judge is filed. If the ruling is contingent upon the availability of an administrative law judge, the parties shall be notified at least 10 days prior to hearing if an administrative law judge will not be available.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.11(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.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.12(17A,272C) Telephone or electronic proceedings. The presiding officer may resolve prehearing matters by telephone conference in which all parties have an opportunity to participate. Contested case hearings will generally not be held by telephone or electronic means in the absence of consent by all parties under compelling circumstances. Nothing shall prohibit a witness from testifying by telephone or electronic means pursuant to subrule 35.26(3).
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.13(17A) Disqualification.

35.13(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. If the licensee elects to appear before the board in the investigation process, the licensee waives this provision.

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.

g. Has any other legally sufficient cause to withdraw from participation in the decision making in that case.

35.13(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 rule 657—35.28(17A,272C).

35.13(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.

35.13(4) *Motion for disqualification.* If a party asserts disqualification on any appropriate ground, including those listed in subrule 35.13(1), the party shall file a motion supported by an affidavit pursuant to Iowa Code section 17A.11(3). 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. The individual against whom disqualification is asserted shall make the initial determination as to whether disqualification is required. If the individual elects not to disqualify, the board shall make the final determination as to disqualification of that individual as part of the record in the case.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.14(17A,272C) Consolidation—severance.

35.14(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.

35.14(2) *Severance.* The presiding officer may, for good cause shown, order any contested case proceedings or portions thereof severed.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.15(17A,272C) Appearance. The respondent or applicant may be represented by an attorney. The attorney must file an appearance in the contested case. If the attorney is not licensed to practice law in Iowa, the attorney must fully comply with Iowa Court Rule 31.14. If the respondent or applicant is an entity, the entity may designate a representative to appear on behalf of the entity.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.16(17A,272C) Answer. An answer may be filed within 20 days of service of the notice of hearing and statement of charges. An answer shall specifically admit, deny, or otherwise answer all

material allegations of the statement of charges to which it responds. It shall state any facts supporting any affirmative defenses and contain as many additional defenses as the respondent may claim. An answer shall state the name, address and telephone number of the person filing the answer. Any allegation in the statement of charges not denied in the answer is considered admitted. The presiding officer may refuse to consider any defense not raised in the answer which could have been raised on the basis of facts known when the answer was filed if any party would be prejudiced.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.17(17A,272C) Service and filing of documents.

35.17(1) *Filing—when required.* After the notice of hearing, all documents in a contested case proceeding shall be filed with the board.

35.17(2) *Filing—how made.* Filing may be made by delivering or mailing the document to the board office located at 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. Filing may also be made by emailing the document to the email addresses identified in the notice of hearing as the appropriate email address for filing. A party electing to file a document via email is responsible for ensuring the document was received.

35.17(3) *Filing—when made.* 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, mailed by first-class mail or state interoffice mail to the board office, so long as there is proof of mailing, or emailed.

35.17(4) *Service—when required.* Except where otherwise provided by law, every document filed in a contested case proceeding shall be simultaneously served upon each of the parties of record to the proceeding, including the assistant attorney general representing the state. Except for 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.

35.17(5) *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, so long as there is proof of mailing.

35.17(6) *Electronic service.* Service may be made upon a party or attorney by email if the person consents in writing in that case to be served in that manner. The written consent shall specify the email address for such service. The written consent may be withdrawn by written notice served on the parties or attorneys.

35.17(7) *Proof of mailing/emailing.* Proof of mailing/emailing 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, 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 the United States mail, state interoffice mail, or email when permitted by 657 IAC 35.17(6).
>
> _____ _____
>
> Date Signature

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17; Editorial change: IAC Supplement 9/8/21]

657—35.18(272C) Investigative file. The board's investigative file is available to the respondent or applicant upon request only after the commencement of a contested case and only prior to the resolution of the contested case. A licensee that elects to enter into a combined statement of charges and settlement agreement is not entitled to request the investigative file. In accordance with Iowa Code

section 272C.6(4), information contained within an investigative file is confidential and may only be used in connection with the disciplinary proceedings before the board.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.19(17A,272C) Discovery.

35.19(1) *Scope.* The scope of discovery described in Iowa Rule of Civil Procedure 1.503 shall apply to contested case proceedings.

35.19(2) *Procedures available.* The following discovery procedures available in the Iowa Rules of Civil Procedure are available to the parties in a contested case proceeding: depositions upon oral examination or written questions; written interrogatories; production of documents, electronically stored information, and things; and requests for admission. Unless lengthened or shortened by the presiding officer, the time frames for discovery in the specific Iowa Rules of Civil Procedure govern those specific procedures.

a. Iowa Rules of Civil Procedure 1.701 through 1.717 regarding depositions shall apply to any depositions taken in a contested case proceeding. Any party taking a deposition in a contested case shall be responsible for any deposition costs, unless otherwise specified or allocated in an order. Deposition costs include, but are not limited to, reimbursement for mileage of the deponent, costs of a certified shorthand reporter, and expert witness fees, as applicable.

b. Iowa Rule of Civil Procedure 1.509 shall apply to any interrogatories propounded in a contested case proceeding.

c. Iowa Rule of Civil Procedure 1.512 shall apply to any requests for production of documents, electronically stored information, and things in a contested case proceeding.

d. Iowa Rule of Civil Procedure 1.510 shall apply to any requests for admission in a contested case proceeding. Iowa Rule of Civil Procedure 1.511 regarding the effect of an admission shall apply in contested case proceedings.

35.19(3) *Disclosure and discovery conference.* The mandatory disclosure and discovery conference requirements in Iowa Rules of Civil Procedure 1.500 and 1.507 do not apply to contested case proceedings. However, upon application by a party, the board may order the parties to comply with these procedures unless doing so would unreasonably complicate the proceedings or impose an undue hardship.

35.19(4) *Experts.* Iowa Rule of Civil Procedure 1.508 shall apply to discovery of any experts identified by a party to a contested case proceeding.

35.19(5) *Service.* Discovery shall be served on all parties to the contested case proceeding but shall not be filed with the board.

35.19(6) *Motions.* A party may file a motion to compel or other motion related to discovery in accordance with this subrule. Any motion filed with the board 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. Motions in regard to discovery shall be ruled upon by the presiding officer. Opposing parties shall be afforded the opportunity to respond within ten days of the filing of the motion unless the time is lengthened or shortened by the presiding officer. The presiding officer may rule on the basis of the written motion and any response or may order argument on the motion.

35.19(7) *Use of evidence.* Evidence obtained in discovery may be used in the contested case proceeding if that evidence would otherwise be admissible in that proceeding.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.20(17A,272C) Issuance of subpoenas in a contested case.

35.20(1) *Types of subpoenas.* 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. Subpoenas shall be issued by the executive director or designee upon a written request that complies with the requirements of this rule. A request for a subpoena of mental health records must confirm that the conditions described in subrule 35.20(3)

have been satisfied prior to the issuance of the subpoena. The executive director or designee may refuse to issue a subpoena if the request does not comply with the requirements of this rule.

35.20(2) *Request for subpoena—contents.* 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:

a. The name, address, and telephone number of the person requesting the subpoena;

b. The name and address of the person to whom the subpoena shall be directed;

c. The date, time, and location at which the person shall be commanded to attend and give testimony;

d. Whether the testimony is requested in connection with a deposition or hearing;

e. A description of the books, papers, records, or other real evidence requested;

f. The date, time, and location for production or inspection and copying; and

g. In the case of a subpoena request for mental health records, confirmation that the conditions described in subrule 35.20(3) have been satisfied.

35.20(3) *Request for subpoena—mental health records.* In the case of a request for a subpoena of mental health records, the request must confirm compliance with the following conditions prior to the issuance of the subpoena:

a. The nature of the issues in the case reasonably justifies the issuance of the requested subpoena;

b. Adequate safeguards have been established to prevent unauthorized disclosure;

c. An express statutory mandate, articulated public policy, or other recognizable public interest favors access; and

d. An attempt was made to notify the patient and to secure an authorization from the patient for the release of the records at issue.

35.20(4) *Content of subpoena.* Each subpoena shall contain, as applicable:

a. The caption of the case;

b. The name, address, and telephone number of the person who requested the subpoena;

c. The name and address of the person to whom the subpoena is directed;

d. The date, time, and location at which the person is commanded to appear;

e. Whether the testimony is commanded in connection with a deposition or hearing;

f. A description of the books, papers, records or other real evidence the person is commanded to produce;

g. The date, time, and location for production or inspection and copying;

h. The time within which a motion to quash or modify the subpoena must be filed;

i. The signature, address, and telephone number of the executive director or designee;

j. The date of issuance;

k. A return of service.

35.20(5) *Distribution of subpoena.* Unless a subpoena is requested to compel testimony or documents for rebuttal or impeachment purposes, the executive director or designee shall mail copies of all subpoenas to the parties. The person who requested the subpoena is responsible for serving the subpoena upon the subject of the subpoena.

35.20(6) *Timely motion.* 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.

35.20(7) *Consideration of motion.* Upon receipt of a timely motion to quash or modify a subpoena, the board may request an administrative law judge to issue a decision, or the board may issue a decision. Oral argument may be scheduled at the discretion of the board or the administrative law judge. The administrative law judge or the board may quash or modify the subpoena, deny the motion, or issue an appropriate protective order.

35.20(8) *Appeal of ruling on motion.* A person aggrieved by a ruling of an administrative law judge who desires to challenge the ruling shall appeal the ruling to the board by serving on the executive director in accordance with rule 657—35.17(17A,272C), a notice of appeal within ten days after service of the decision of the administrative law judge.

35.20(9) *Judicial review.* If the person contesting the subpoena is not a party to the contested case proceeding, the board's decision is final for purposes of judicial review. If the person contesting the subpoena is a party to the contested case proceeding, the board's decision is not final for purposes of judicial review until there is a final decision in the contested case.

35.20(10) *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.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.21(17A,272C) Motions.

35.21(1) *Form.* No technical form for motions is required. Prehearing motions must be in writing, state the grounds for relief, and state the relief sought.

35.21(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.

35.21(3) *Oral argument.* The presiding officer may schedule oral argument on any motion.

35.21(4) *Timely filing.* Motions pertaining to the hearing 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.

35.21(5) *Dispositive motions.* Dispositive motions, such as motions for summary judgment or motions to dismiss, must be filed with the board and served on all parties to the contested case proceeding at least 30 days prior to the scheduled hearing date, unless otherwise ordered or permitted by the presiding officer. Any party may file a written response to a dispositive motion within 10 days after the motion is served, unless the time for response is otherwise lengthened or shortened by the presiding officer.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.22(17A,272C) Prehearing conference.

35.22(1) *Request or order for conference.* Any party may request a prehearing conference. Prehearing conferences shall be conducted by the executive director, who may request that an administrative law judge conduct the prehearing conference. A written request for prehearing conference or an order for prehearing conference on the executive director's own motion shall be filed not less than seven days prior to the hearing date, unless authorized by the person conducting the prehearing conference. A prehearing conference shall be scheduled not less than three business days prior to the hearing date.

35.22(2) *Conference subjects.* Each party shall be prepared to discuss the following subjects at the prehearing conference:

a. Submission of expert and other witness lists. Witness lists may be amended subsequent to the prehearing conference within the time limits established by the executive director or administrative law judge at the prehearing conference. Any such amendments must be served on all parties. Witnesses not listed on the final witness list may be excluded from testifying unless there was good cause for the failure to include their names.

b. Submission of exhibit lists. Exhibit lists may be amended subsequent to the prehearing conference within the time limits established by the executive director or administrative law judge at the prehearing conference. Other than rebuttal exhibits, exhibits that are not listed on the final exhibit list may be excluded from admission into evidence unless there was good cause for the failure to include them.

c. The entry of a scheduling order to include deadlines for completion of discovery.

d. Stipulations of law or fact.

e. Stipulations on the admissibility of exhibits.

f. Identification of matters which the parties intend to request be officially noticed.

g. Consideration of any additional matters which will expedite the hearing.

35.22(3) *Conducted by telephone.* Prehearing conferences shall be conducted by telephone unless otherwise ordered.

35.22(4) *Intra-agency appeal.* A party must seek intra-agency appeal to the board of prehearing rulings made by an administrative law judge in order to adequately exhaust administrative remedies. Such appeals must be filed within ten days of the date of the issuance of the challenged ruling but no later than the time for compliance with the order or the date of hearing, whichever is first.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.23(17A,272C) Continuances. Unless otherwise provided, requests for continuances shall be filed with the board.

35.23(1) *Requirements of request.* A written request 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 attorney.

35.23(2) *Notice to parties.* No request for continuance shall be made or granted without notice to all parties except in an emergency where notice is not feasible. The presiding officer may allow an oral application for continuance at the contested case hearing only in the event of an unanticipated emergency.

35.23(3) *Authorized individuals.* The presiding officer or the executive director has the authority to grant or deny a request for a continuance in accordance with this subrule. The executive director or an administrative law judge may enter an order granting an uncontested request for a continuance. Upon consultation with the board chair, the executive director or an administrative law judge may deny an uncontested request for a continuance or may rule on a contested request for continuance.

35.23(4) *Consideration of request.* In determining whether to grant a continuance, the presiding officer or the executive director may require documentation of any grounds for a continuance and may consider:

a. Prior continuances;

b. The interests of all parties;

c. The public interest;

d. The likelihood of settlement;

e. The existence of an emergency;

f. Any objection;

g. Any applicable time requirements;

h. The existence of a conflict in the schedules of counsel, parties, or witnesses;

i. The timeliness of the request; and

j. Other relevant factors.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.24(17A,272C) Settlement agreements.

35.24(1) *Initiation and participation.* A contested case may be resolved by settlement agreement. Settlement negotiations may be initiated by any party at any stage of a contested case. No party is required to participate in the settlement process.

35.24(2) *Assistant attorney general and board chair discussion of possible settlement.* If the respondent initiates or consents to settlement negotiations, the assistant attorney general prosecuting the case may discuss settlement with the board chair without violating the prohibition against ex parte communications in Iowa Code section 17A.17 and without disqualifying the board chair from participating in the adjudication of the contested case. The full board shall not be involved in settlement

negotiations until a proposed settlement agreement executed by the respondent is submitted to the board for approval.

35.24(3) *Board consideration of proposed settlement.* By signing the proposed settlement agreement, the respondent authorizes an assistant attorney general to have ex parte communications with the board related to the terms of the proposed settlement. If the board fails to approve the proposed settlement agreement, it shall be of no force or effect to either party and shall not be admissible at hearing. Upon rejecting a proposed settlement agreement, the board may suggest alternative terms of settlement, which the respondent is free to accept or reject.

35.24(4) *Public record.* A settlement agreement is a permanent public record open for inspection under Iowa Code chapter 22.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.25(17A,124B,126,147,155A,205,272C) Hearing procedures in contested cases.

35.25(1) *Presiding officer.* The presiding officer shall be in control of the proceedings and shall have the authority to administer oaths and to admit or exclude testimony or evidence and shall rule on all motions and objections. The board may request that an administrative law judge assist the board by performing any of these functions.

35.25(2) *Panel of specialists.* When, in the opinion of the board, it is desirable to obtain specialists within an area of practice when holding disciplinary hearings, the board may appoint a panel of three specialists who are not board members to make findings of fact and to report to the board. Such findings shall not include any recommendation for or against licensee discipline.

35.25(3) *Right of participation or representation.* An applicant or respondent has the right to participate or to be represented in all hearings related to the party's case. Partnerships, corporations, or associations may be represented by any member, officer, director, or duly authorized agent. Any applicant or respondent may be represented by an attorney at the party's own expense.

35.25(4) *Objections.* All objections shall be timely made and stated on the record.

35.25(5) *Rights of all parties.* Subject to terms 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, submit briefs, and engage in oral argument.

35.25(6) *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.

35.25(7) *Sequestering witnesses.* Witnesses may be sequestered during the hearing.

35.25(8) *Appeal of administrative law judge rulings.* All rulings by an administrative law judge who acts either as presiding officer or as an aid to the board are subject to appeal to the board. While a party may seek immediate board review of rulings made by an administrative law judge when the administrative law judge is sitting with and acting as an aid to the board or panel of specialists during a hearing, such immediate review is not required to preserve error for judicial review.

35.25(9) *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 board members and administrative law judge have the right to question a witness. 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.

35.25(10) *Open/closed hearing and protective order.* The hearing shall be open to the public unless the respondent requests that the hearing be closed, in accordance with Iowa Code section 272C.6(1). At

the request of either party, or on the board's own motion, the presiding officer may issue a protective order to protect documents which are privileged or confidential by law.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.26(17A,272C) Evidence.

35.26(1) *General.*

a. Relevant evidence is admissible, subject to the discretion of the presiding officer. Irrelevant, immaterial and unduly repetitious evidence should be excluded. A finding will be based upon the kind of evidence on which reasonably prudent persons are accustomed to rely for the conduct of their serious affairs, and may be based on hearsay or other types of evidence which may or would be inadmissible in a jury trial.

b. 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.

c. Stipulation of facts is encouraged. The presiding officer may make a decision based on stipulated facts.

d. 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.

e. 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.

f. 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.

35.26(2) *Exhibits.*

a. 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. Copies of admitted documents should be distributed to individual board members and the administrative law judge. Unless prior arrangements have been made, the party seeking admission of a document should arrive at the hearing prepared with sufficient copies of the document to distribute to opposing parties, board members, the administrative law judge, and witnesses who are expected to examine the document. The state's exhibits shall be marked numerically, and the applicant's or respondent's exhibits shall be marked alphabetically.

b. All exhibits admitted into evidence shall be appropriately marked and be made part of the record.

c. An original is not required to prove the content of a writing, recording, or photograph. Duplicates or photocopies are admissible. Any objection related to the authenticity of an exhibit shall go to the weight given to that exhibit and not preclude its admissibility.

35.26(3) *Witnesses.*

a. Witnesses may be sequestered during the hearing.

b. Subject to the terms prescribed by the presiding officer and the limitations in Iowa Rule of Civil Procedure 1.704, parties may present the testimony of witnesses in person, by telephone, by videoconference, by affidavit, or by written or video deposition. If a witness is providing testimony in person, by telephone, or by videoconference, use of any deposition is limited by Iowa Rule of Civil Procedure 1.704.

c. Witnesses are entitled to be represented by an attorney at their own expense. In a closed hearing, the attorney may be present only when the client testifies. The attorney may assert legal privileges personal to the client, but may not make other objections. The attorney may only ask questions of the client to prevent a misstatement from being entered into the record.

d. The parties in a contested case shall be responsible for any witness fees and expenses incurred by witnesses appearing at the contested case hearing, unless otherwise specified or allocated in an order. The costs for lay witnesses shall be determined in accordance with Iowa Code section 622.69. The costs for expert witnesses shall be determined in accordance with Iowa Code section 622.72. Witnesses are entitled to reimbursement for mileage and may be entitled to reimbursement for meals and lodging, as incurred.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.27(17A,272C) Default.

35.27(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.

35.27(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.

35.27(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 657—35.30(17A,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.

35.27(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.

35.27(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.

35.27(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 1.971.

35.27(7) *Appeal of decision on motion to vacate.* A decision by an administrative law judge granting or denying a motion to vacate is subject to appeal to the board within 20 days.

35.27(8) *Notice of hearing.* If a motion to vacate is granted and no timely appeal to the board has been filed, the presiding officer shall issue a rescheduling order setting a new hearing date and the contested case shall proceed accordingly.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.28(17A,272C) Ex parte communication.

35.28(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 35.13(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.

35.28(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.

35.28(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.

35.28(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 657—35.17(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.

35.28(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.

35.28(6) *Others authorized to communicate with presiding officer.* The executive 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 35.28(1).

35.28(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 657—35.23(17A,272C).

35.28(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.

35.28(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.

35.28(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 director for possible sanctions including censure, suspension, dismissal, or other disciplinary action.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.29(17A,272C) Recording costs. Contested case hearings shall be recorded by electronic means or by a certified shorthand reporter. The board may assess the costs of the certified shorthand reporter to the licensee in a disciplinary hearing which results in disciplinary action taken against the licensee by the board in accordance with 657—subrule 36.10(2). 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. If the request for the hearing record is made as a result of a petition for judicial review, the party who filed the petition shall be considered the requesting party.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.30(17A,272C) Proposed decisions. Decisions issued by an administrative law judge in nondisciplinary cases are proposed decisions. A proposed decision issued by an administrative law judge becomes a final decision if not timely appealed or reviewed in accordance with this rule.

35.30(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.

35.30(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.

35.30(3) *Exhaustion.* A party must timely seek intra-agency appeal of a proposed decision in order to adequately exhaust administrative remedies.

35.30(4) *Notice of appeal.* An appeal of a proposed decision is initiated by filing a timely notice of appeal with the board. The notice of appeal must be signed by the appealing party or an attorney for that party and contain a certificate of service. The notice shall specify:

a. The parties initiating the appeal;

b. The proposed decision or order which is being appealed;

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.

35.30(5) *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 nonappealing 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.

35.30(6) *Scheduling.* The board shall issue a schedule for consideration of the appeal.

35.30(7) *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.

35.30(8) *Record.* The record on appeal or review shall be the entire record made before the administrative law judge.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.31(17A) Final decision.

35.31(1) *Contents.* A final decision of the board shall include findings of fact and conclusions of law. When the board presides over the reception of the evidence at the hearing, its decision is a final decision.

35.31(2) *Hearing fee and costs.* The board may charge a hearing fee and assess other costs to the licensee for conducting a disciplinary hearing which results in disciplinary action taken against the licensee by the board in accordance with 657—subrule 36.10(2).

35.31(3) *Method of service.* Final decisions shall be served on the respondent or applicant using one of the following methods:

a. Personal service, as provided in the Iowa Rules of Civil Procedure.

b. Certified mail, return receipt requested.

c. Signed acknowledgment accepting service.

d. When service cannot be accomplished using the above methods:

(1) An affidavit shall be prepared outlining the measures taken to attempt service; and

(2) The final decision shall be published once each week for three consecutive weeks in a newspaper of general circulation, published or circulated in the county of last-known residence of the respondent.

e. If the respondent or applicant is represented by an attorney, the final decision shall be mailed to the attorney. The attorney may waive the requirement to serve the respondent or applicant through a written acknowledgment that the attorney is accepting service on behalf of the client. The state shall be served by first-class mail or state interoffice mail.

35.31(4) *Public record.* A final decision is a permanent public record open for inspection under Iowa Code chapter 22, in accordance with Iowa Code section 272C.6(4).

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.32(17A,124B,126,147,155A,205,272C) Applications for rehearing.

35.32(1) *By whom filed.* Any party to a contested case proceeding may file an application for rehearing from a final order.

35.32(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, upon showing good cause, the applicant requests an opportunity to submit additional evidence. A party may request the taking of additional evidence after the issuance of a final order only by establishing that:

a. The evidence is material; and

b. The evidence arose after the completion of the original hearing; or

c. Good cause exists for failure to present the evidence at the original hearing; and

d. The party has not waived the right to present additional evidence.

35.32(3) *Time of filing.* The application shall be filed with the board within 20 days after issuance of the final decision.

35.32(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 shall serve copies on all parties.

35.32(5) *Disposition.* Any application for a rehearing shall be deemed denied unless the board grants the application within 20 days after its filing.

35.32(6) *Only remedy.* Application for rehearing is the only procedure by which a party may request that the board reconsider a final board decision.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.33(17A,272C) Stays of board actions.

35.33(1) *When available.* Any party to a contested case proceeding may petition the board for a stay of an order issued in that proceeding or for other temporary remedies, pending review by the board or pending judicial review. The petition shall state the reasons justifying a stay or other temporary remedy. The petition must be filed within 30 days of the issuance of the final order, or if a party filed a request for rehearing that was denied, the petition must be filed within 30 days after the request for rehearing was denied or deemed denied.

35.33(2) *When granted.* The board shall not grant a stay in any case in which the district court would be expressly prohibited by statute from granting a stay. 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.

35.33(3) *Exhaustion required.* A party must petition the board for a stay pursuant to this rule prior to requesting a stay from the district court in a judicial review proceeding.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.34(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.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.35(17A,124B,126,147,155A,205,272C) Emergency adjudicative proceedings.

35.35(1) *Necessary emergency action.* To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, the board may issue a written order in compliance with Iowa Code section 17A.18A to suspend a license 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.

35.35(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 served on persons who are required to comply with the order by utilizing one or more of the following procedures:

(1) Personal service, as provided in the Iowa Rules of Civil Procedure; or

(2) Certified restricted mail, return receipt requested; or

(3) Signed acknowledgment accepting service.

c. To the degree practicable, the board shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

35.35(3) *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 and electronic mail the persons who are required to comply with the order.

35.35(4) *Completion of proceedings.* 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, the licensee subject to the emergency adjudicative order may request a continuance of the hearing at any time by filing a request with the board. The state may only file a request for a continuance in compelling circumstances. Nothing in this subrule shall be construed to eliminate the opportunity to resolve the matter with a settlement agreement.

35.35(5) *Public record.* An emergency adjudicative order is a permanent public record open for inspection under Iowa Code chapter 22.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.36(17A,147,272C) Application for reinstatement. Any person whose license has been revoked or has been voluntarily surrendered may apply for reinstatement. An application for reinstatement must be made in accordance with the terms specified in the board's order of revocation or order accepting the voluntary surrender. Any person whose license has been suspended and the board order imposing the suspension indicates that the respondent must apply for and receive reinstatement may apply for reinstatement in accordance with the terms specified in the board's order. All applications for reinstatement must be filed in accordance with this rule.

35.36(1) *Timing of application.* If the order for revocation, suspension, or acceptance of surrender of a license did not establish terms for reinstatement, an initial application for reinstatement may not be filed until at least one year has elapsed from the date of issuance of the order. Persons who have failed to satisfy the terms imposed by the board order revoking, suspending, or accepting surrender of a license shall not be entitled to apply for reinstatement.

35.36(2) *Initiated by respondent.* Reinstatement proceedings shall be initiated by the respondent, who shall file with the board an application for reinstatement of the respondent's license. Such application shall be docketed in the original contested case in which the license was revoked, suspended, or surrendered. The person filing the application for reinstatement shall immediately serve a copy upon the office of the attorney general and shall serve any additional documents filed in connection with the application.

35.36(3) *Contents.* The application shall allege facts and circumstances which, if established, will be sufficient to enable the board to determine that the basis for the revocation, suspension, or surrender no longer exists and that it shall be in the public interest for the license to be reinstated. The application shall include written evidence supporting the respondent's assertion that the basis for the revocation, suspension, or surrender no longer exists and that it shall be in the public interest for the license to be reinstated. Such evidence may include, but is not limited to, medical and mental health records establishing successful completion of any necessary medical or mental health treatment and aftercare recommendations; documentation verifying successful completion of any court-imposed terms of probation; statements from support group sponsors verifying active participation in a support group; verified statements from current and past employers attesting to employability; and evidence establishing that prior professional competency or unethical conduct issues have been resolved. The burden of proof to establish such facts shall be on the respondent.

35.36(4) *Review for conformity.* The executive director or designee shall review the application for reinstatement and determine if it conforms to the terms established in the board order that revoked, suspended, or accepted surrender of the license and the requirements imposed by this rule. Applications failing to comply with the specified terms or with the requirements in this rule will be denied. Such denial shall be in writing, stating the grounds, and may be appealed by requesting a hearing before the board.

35.36(5) *Hearing and order.* Applications not denied for failure to conform to the terms established in the board order that revoked, suspended, or accepted surrender of the license or requirements imposed by this rule may be set for hearing before the board. The hearing shall be a contested case hearing within the meaning of Iowa Code section 17A.12, and the order to grant or deny reinstatement shall incorporate findings of fact and conclusions of law. If reinstatement is granted, terms may be imposed. Such terms may include, but are not limited to, requiring the licensee to retake and pass an examination required for initial licensure, requiring the licensee to complete continuing education, restricting the licensee from engaging in a particular practice, and imposing a probationary term with monitoring requirements. Nothing shall prohibit the board from issuing an order granting reinstatement without terms, or from entering into a stipulated order granting reinstatement with terms, in the absence of a hearing.

35.36(6) *License reactivation.* A licensee whose license is reinstated must complete the requirements for license reactivation in order to receive an active license.

35.36(7) *Public record.* An order granting or denying reinstatement is a permanent public record open for inspection under Iowa Code chapter 22.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—35.37(17A,22,272C) Dissemination of public records. All documents identified in this chapter as permanent public records open for inspection under Iowa Code chapter 22 are reported to national databanks in accordance with applicable reporting requirements. In addition, these documents may be posted on the board's website, published in the board's newsletter, distributed to national or state associations, transmitted to mailing lists or news media, issued in conjunction with a press release, or otherwise disseminated.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17; Editorial change: IAC Supplement 9/8/21]

657—35.38(17A) Judicial review. Judicial review of a final order of the board may be sought in accordance with the terms of Iowa Code chapter 17A.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

These rules are intended to implement Iowa Code sections 17A.10 to 17A.23, 124.304, 124B.12, 126.17, 147.55, 155A.6 to 155A.6B, 155A.12, 155A.13 to 155A.13C, 155A.15 to 155A.18, 155A.26, 205.11, 272C.3 to 272C.6, 272C.9, and 272C.10.

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[Editorial change: IAC Supplement 9/8/21]

CHAPTER 36
DISCIPLINE

657—36.1(147,155A,272C) Authority. The board has the authority to impose discipline for any violations of Iowa Code chapters 124, 124B, 126, 147, 155A, 205, and 272C or the rules promulgated thereunder.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—36.2(147,155A,272C) Definitions. For purposes of this chapter:

"Board" means the Iowa board of pharmacy.

"License" means any license, registration, or permit issued by the board, regardless of whether the license, registration, or permit is active.

"Licensee" means any person or entity possessing a license, registration, or permit issued by the board, regardless of whether the license, registration, or permit is active.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—36.3(147,155A,272C) Complaints, investigations, and board action.

36.3(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 may violate the board's rules or that are related to the ethical or professional conduct of a licensee.

36.3(2) *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 discipline shall be confidential pursuant to Iowa Code section 272C.6(4).

36.3(3) *Investigation of allegations.* In order to determine if probable cause exists for a disciplinary hearing, the board, the executive director, or someone designated by the executive director shall cause an investigation to be made into the allegations of the complaint. The licensee that is the subject of the complaint shall be given a reasonable opportunity to present to the investigator a position or defense respecting the allegations of the complaint prior to the commencement of a contested case.

36.3(4) *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, which are necessary for the board to decide whether to institute a contested case proceeding. The issuance of investigative subpoenas is governed by rule 657—36.4(17A,147,152,272C).

36.3(5) *Investigative report.* Upon completion of the investigation, the investigator(s) shall prepare a report for the board's consideration. The report may contain evidence gathered by the investigator, findings made by the investigator, the licensee's response to the allegations, and the applicable laws or rules alleged to have been violated.

36.3(6) *Board consideration.* The board shall review all investigations. Participation in the review of investigative materials shall not bar any board member from participating in any subsequent disciplinary proceeding.

a. Board action. After reviewing an investigation, the board may institute a disciplinary proceeding by filing one or more statements of charges, approve a combined statement of charges and settlement agreement, send a confidential letter of education or administrative warning to the licensee, request additional investigation, including peer review, refer the case to another regulatory authority with jurisdiction over the issue, 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. The purpose of a confidential letter of education or administrative warning is to alert the licensee to possible violations of Iowa law or board rules so that the licensee may address the issues. Confidential letters of education and administrative warnings do not constitute formal disciplinary action and are not open for inspection under Iowa Code chapter 22. The board shall maintain a copy of the confidential letter of education or administrative warning in the confidential investigative file regarding the licensee.

Confidential letters of education and administrative warnings may be used as evidence against a licensee in future administrative hearings.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—36.4(17A,147,152,272C) Issuance of investigatory subpoenas. The board shall have the authority to issue an investigatory subpoena in accordance with the provisions of Iowa Code section 17A.13.

36.4(1) *Justification.* The executive director or designee may, upon the written request of a board investigator or on the executive director's own initiative, subpoena books, papers, records and other real evidence which 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:

a. The nature of the complaint reasonably justifies the issuance of a subpoena;

b. Adequate safeguards have been established to prevent unauthorized disclosure;

c. An express statutory mandate, articulated public policy, or other recognizable public interest favors access; and

d. An attempt was made to notify the patient and to secure an authorization from the patient for release of the records at issue.

36.4(2) *Contents of request.* A written request for a subpoena or the executive director's written memorandum in support of the issuance of a subpoena shall contain the following:

a. The name and address of the person to whom the subpoena will be directed;

b. A specific description of the books, papers, records or other real evidence requested;

c. 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

d. In the case of a subpoena request for mental health records, confirmation that the conditions described in subrule 36.4(1) have been satisfied.

36.4(3) *Contents of subpoena.* Each subpoena shall contain the following:

a. The name and address of the person to whom the subpoena is directed;

b. A description of the books, papers, records or other real evidence requested;

c. The date, time and location for production or inspection and copying;

d. The time within which a motion to quash or modify the subpoena must be filed;

e. The signature, address and telephone number of the executive director or designee;

f. The date of issuance;

g. A return of service.

36.4(4) *Motion to quash or modify.* Any person who is aggrieved or adversely affected by compliance with the subpoena and who desires to challenge the subpoena must, 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.

36.4(5) *Timely filing of motion.* Upon receipt of a timely motion to quash or modify a subpoena, the board may request an administrative law judge to issue a decision or the board may issue a decision. Oral argument may be scheduled at the discretion of the board or the administrative law judge. The administrative law judge or the board may quash or modify the subpoena, deny the motion, or issue an appropriate protective order.

36.4(6) *Appeal of administrative law judge ruling.* A person aggrieved by a ruling of an administrative law judge who desires to challenge that ruling must appeal the ruling to the board by filing a notice of appeal with the board within ten days after service of the decision of the administrative law judge in accordance with rule 657—35.17(17A,272C).

36.4(7) *Judicial review.* 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

(1) the person is notified that the investigation has been concluded with no formal action, or (2) there is a final decision in the contested case.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—36.5(147,272C) Peer review committee. Any case may be referred to peer review for evaluation of the professional services rendered by the licensee.

36.5(1) *Contract and case referral.* The board shall enter into a contract with peer reviewers to provide peer review services. The board or board staff shall determine which peer reviewer(s) will review a case and what investigative information shall be referred to a peer reviewer.

36.5(2) *Written opinion.* Peer reviewers shall review the information provided by the board and provide a written report to the board. The written report shall contain an opinion of the peer reviewer regarding whether the licensee conformed to minimum standards of acceptable and prevailing practice of pharmacy and the rationale supporting the opinion.

36.5(3) *Confidentiality.* Peer reviewers shall observe the confidentiality requirements imposed by Iowa Code section 272C.6(4).

36.5(4) *Board review and action.* The board shall review the committee's findings and proceed with action available under subrule 36.3(6).
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—36.6(147,155A,272C) Grounds for discipline. The board may impose any of the disciplinary sanctions set forth in rule 657—36.7(147,155A,272C) when the board determines that the licensee has committed any of the following acts or omissions:

36.6(1) 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, a pharmacy technician, or a pharmacy support person. Fraud in procuring a license 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.

36.6(2) Professional incompetency. Professional incompetency includes but is not limited to:

a. A substantial lack of knowledge or ability to discharge professional obligations within the scope of the pharmacist's practice.

b. 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.

c. 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.

d. 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.

36.6(3) 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.

36.6(4) Habitual intoxication or addiction to the use of drugs. Habitual intoxication or addiction to the use of drugs includes, but is not limited to:

a. The inability of a licensee to practice with reasonable skill and safety by reason of the excessive use of alcohol on a continuing basis.

b. The excessive use of drugs which may impair a licensee's ability to practice with reasonable skill or safety.

36.6(5) Being convicted of an offense that directly relates to the duties and responsibilities of the profession. A conviction includes a guilty plea, including Alford and nolo contendere pleas, or a finding

or verdict of guilt, even if the adjudication of guilt is deferred, withheld or not entered. A copy of the guilty plea or order of conviction constitutes conclusive evidence of conviction. An offense directly relates to the duties and responsibilities of the profession if the actions taken in furtherance of the offense are actions customarily performed within the scope of practice of the profession or the circumstances under which the offense was committed are circumstances customary to the profession.

36.6(6) 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.

36.6(7) Use of untrue or improbable statements in advertisements.

36.6(8) 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.

36.6(9) Willful or repeated violations of the provisions of Iowa Code chapter 147 or 272C. Willful or repeated violations of these Acts include, but are not limited to, a licensee's intentionally or repeatedly violating a lawful rule or regulation promulgated by the board of pharmacy or the Iowa 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 Iowa Code.

36.6(10) 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.

36.6(11) 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 revocation, suspension, or other disciplinary sanction.

36.6(12) Knowingly aiding, assisting, procuring, or advising another person to unlawfully practice pharmacy or to unlawfully perform the functions of a pharmacist-intern, a pharmacy technician, or a pharmacy support person.

36.6(13) Inability of a licensee to practice with reasonable skill and safety by reason of mental or physical impairment or chemical abuse.

36.6(14) Being adjudged mentally incompetent by a court of competent jurisdiction. Such adjudication shall automatically suspend a license for the duration of the license or registration unless the board otherwise orders.

36.6(15) Submission of a false report of continuing education, submission of a false certification of completion of continuing education, or failure to submit biennial reports of continuing education as directed by the board.

36.6(16) Failure to notify the board within 30 days after occurrence of any judgment or settlement of a malpractice court claim or action.

36.6(17) Failure to file reports concerning acts or omissions committed by another licensee.

36.6(18) Willful or repeated malpractice.

36.6(19) Willful or gross negligence.

36.6(20) Obtaining any fee by fraud or misrepresentation.

36.6(21) Violating any of the grounds for revocation or suspension of a license or registration listed in Iowa Code section 147.55, Iowa Code chapter 155A, or any of the rules of the board.

36.6(22) 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, operating an outsourcing facility without a current outsourcing facility license, practicing as a pharmacist-intern without a current pharmacist-intern registration, assisting a pharmacist with technical functions associated with the practice of pharmacy without a current pharmacy technician registration except as provided in the introductory paragraph of rule 657—3.3(155A), or assisting a pharmacist with nontechnical functions associated with the practice of pharmacy without a current pharmacy support person registration.

36.6(23) Attempting to circumvent the patient counseling requirements or discouraging patients from receiving patient counseling concerning their prescription drug orders.

36.6(24) 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.

36.6(25) Engaging in any conduct that subverts or attempts to subvert a board investigation.

36.6(26) Employing or continuing to employ as a practicing pharmacist any person whose Iowa pharmacist license is not current and active, 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 the introductory paragraph of rule 657—3.3(155A), or employing or continuing to employ a person to assist a pharmacist with nontechnical functions associated with the practice of pharmacy who is not currently registered as a pharmacy support person.

36.6(27) Retaliating against a pharmacist, pharmacist-intern, pharmacy technician, or pharmacy support person for making allegations of illegal or unethical activities, making required reports to the board, or cooperating with a board investigation or survey.

36.6(28) Failing to create and maintain complete and accurate records as required by state or federal law or regulation or rule of the board.

36.6(29) Violating the pharmacy or drug laws or rules of another state while under the jurisdiction of that state.

36.6(30) Having a license revoked or suspended or having other disciplinary action taken by a licensing authority of this state or of another state, territory, or country for conduct substantially equivalent to any of the grounds for disciplinary action in Iowa. A copy of the record from the licensing authority taking the disciplinary action shall be conclusive evidence of the action.

36.6(31) Failure to comply with mandatory child or dependent adult abuse reporter training requirements.

36.6(32) Failure to timely provide to the board or a representative of the board prescription fill data or other required pharmacy or controlled substances records.

36.6(33) Nonpayment of a state debt as evidenced by a certificate of noncompliance issued pursuant to Iowa Code chapter 272D.

36.6(34) Failure to notify the board of a criminal conviction relating to the practice of pharmacy or to the distribution of drugs within 30 days of the action, regardless of the jurisdiction where it occurred.

36.6(35) Obtaining, possessing, or attempting to obtain or possess prescription drugs without lawful authority.

36.6(36) Diverting prescription drugs from a pharmacy for personal use or for distribution.

36.6(37) Practicing pharmacy, or assisting in the practice of pharmacy, while under the influence of alcohol or illicit substances.

36.6(38) Practicing pharmacy, or assisting in the practice of pharmacy, while under the influence of prescription drugs or substances for which the licensee does not have a lawful prescription or while impaired by the use of legitimately prescribed pharmacological agents, drugs, or substances.

36.6(39) Forging or altering a prescription.

36.6(40) Practicing outside the scope of the profession.

36.6(41) Dispensing, or contributing to the dispensing of, an incorrect prescription, which includes, but is not limited to, the incorrect drug, the incorrect strength, the incorrect patient or prescriber, or the incorrect or incomplete directions.

36.6(42) Failing to comply with a confidential order for evaluation.

36.6(43) Failing to comply with the terms of an initial agreement or contract with the Iowa monitoring program for pharmacy professionals committee.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17; **ARC 4581C**, IAB 7/31/19, effective 9/4/19; **ARC 5750C**, IAB 7/14/21, effective 8/18/21]

657—36.7(147,155A,272C) Disciplinary sanctions.

36.7(1) *Possible sanctions.* The board has the authority to impose the following disciplinary sanctions:

a. Revocation of a license issued by the board.

b. Suspension of a license issued by the board until further order of the board or for a specified period.

c. Nonrenewal of 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 licensee to complete additional education or training.

g. Require a pharmacist to successfully complete any reexamination for licensure.

h. Order a licensee 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.

36.7(2) *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.

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—36.8(147,272C) Voluntary surrender. A voluntary surrender of a license may be submitted to the board as resolution of a contested case or in lieu of continued compliance with a disciplinary order of the board. A voluntary surrender, when accepted by the board, has the same force and effect as an order of revocation. The voluntary surrender of a license during the pendency of a complaint or investigation shall be considered discipline and shall have the same force and effect as an order of revocation. A request for reinstatement of a license that has been surrendered shall be handled under the terms established by rule 657—35.36(17A,147,272C).

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—36.9(155A,272C) Order for mental or physical examination. A licensee is, as a condition of licensure, 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 licensee.

36.9(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 licensee must submit.

b. The name and address of the examiner or treatment facility that the board has identified as having the potential to perform the examination.

c. The time period in which the licensee must schedule the required examination.

d. The amount of time in which the licensee is required to complete the examination.

e. A requirement that the licensee cause a report of the examination results to be provided to the board within a specified period of time.

f. A requirement that the licensee communicate with the board regarding the status of the examination.

g. A provision allowing the licensee 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.

36.9(2) *Objection to order.* A licensee 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 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 confidentiality.

36.9(3) *Closed hearing.* Any hearing on an objection to the board order shall be closed pursuant to Iowa Code section 272C.6(4).

36.9(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).

[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—36.10(272C) Disciplinary hearings—fees and costs.

36.10(1) *Definitions.* As used in this chapter in relation to a formal disciplinary action filed by the board against a licensee:

"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 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.

36.10(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 licensee. In addition to the fee, the board may recover from the licensee costs for the following procedures and personnel:

a. Recording fees of a certified shorthand reporter.

b. Transcript.

c. Witness fees and expenses.

d. Depositions.

36.10(3) *Fees, costs as part of disciplinary order.* Fees and costs assessed by the board shall be described as part of the board's final disciplinary order. Fees and costs that can be calculated at the time of the issuance of the board's final disciplinary order shall be itemized in the order. Fees and costs that cannot be calculated at the time of the issuance of the board's final disciplinary order may be invoiced to the licensee at a later time, provided that the board's final disciplinary order states that the particular fees and costs will be invoiced at a later date. The board's final disciplinary order and any invoices shall specify the time period in which the licensee shall pay the assessed fees and costs.

36.10(4) *Board treatment of collected fees, costs.* Fees and costs collected by the board 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.

36.10(5) *Failure to pay assessed fees, costs.* Failure of a licensee to pay the fees and costs assessed herein within the time period specified in the board's final disciplinary order or subsequent invoice shall constitute a violation of a lawful order of the board.
[**ARC 3344C**, IAB 9/27/17, effective 11/1/17]

657—36.11(88GA,SF304) Prohibited grounds for discipline. The board shall not suspend or revoke the license of a person who is in default or is delinquent on repayment or a service obligation under federal or state postsecondary educational loans or public or private services-conditional postsecondary tuition assistance solely on the basis of such default or delinquency.
[**ARC 4581C**, IAB 7/31/19, effective 9/4/19]

These rules are intended to implement Iowa Code sections 17A.10 to 17A.23, 124.304, 124B.12, 126.17, 147.55, 155A.6 to 155A.6B, 155A.12, 155A.13 to 155A.13C, 155A.15 to 155A.18, 155A.26, 205.11, 272C.3 to 272C.6, 272C.9, and 272C.10.

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[1] April 30, 2008, effective date of 36.1(4)*"i," "v,"* and *"aa"* delayed 70 days by the Administrative Rules Review Committee at its meeting held April 4, 2008.

CHAPTER 37
IOWA PRESCRIPTION MONITORING PROGRAM

657—37.1(124) Purpose and scope. These rules establish a prescription monitoring program (PMP) that compiles a central database of reportable prescriptions dispensed to patients in Iowa. An authorized health care practitioner shall access PMP information when mandated by the practitioner's licensing authority 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 practitioner with a resource for information regarding a patient's use of controlled substances and to serve as a tool to assess a prescriber's prescribing practices. 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 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.2(124) Definitions. For the purposes of this chapter, the following definitions shall apply.

"Administer" means to provide or apply a controlled substance to a patient for immediate use within the prescribing practitioner's practice location. Administration does not include dispensing.

"Board" means the Iowa board of pharmacy.

"Client" means the owner, owner's designee, or other person responsible for an animal patient.

"Controlled substance" means a drug in Schedules II 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.

"CSA registration" means registration with the board under the Iowa uniform controlled substances Act pursuant to 657—Chapter 10.

"DEA number" means the registration number issued to an individual or pharmacy by the U.S. Department of Justice, Drug Enforcement Administration (DEA), authorizing the individual or pharmacy to engage in the prescribing, dispensing, distributing, or procuring of a controlled substance.

"Dispense" means to provide a controlled substance to a patient for self-use outside of the prescribing practitioner's practice location. Dispensing does not include administration.

"Dispenser" means a pharmacy or prescriber, regardless of location, who delivers to the ultimate user a substance required to be reported to the PMP. "Dispenser" does not include a person exempt from reporting pursuant to subrule 37.7(2).

"First responder" means an emergency medical care provider, a registered nurse staffing an authorized service program under Iowa Code section 147A.12, a physician assistant staffing an authorized service program under Iowa Code section 147A.13, a firefighter, or a peace officer as defined in Iowa Code section 801.4, who is trained and authorized to administer an opioid antagonist.

"Health care facility" means a residential care facility, a nursing facility, an intermediate care facility for persons with mental illness, or an intermediate care facility for persons with an intellectual disability.

"Health care professional" means a person who, by certification, registration, or licensure, is qualified to provide and is engaged in providing health care to patients. "Health care professional" does not include clerical or administrative staff. A health care professional shall be credentialed in a manner that permits verification and regulation of the health care professional's credentials.

"Health care system" means an organization that includes at least one hospital or at least one group of practitioners that provides comprehensive care that are connected with each other through common ownership or management.

"HIPAA" means the Health Insurance Portability and Accountability Act.

"Law enforcement" means an entity or agency with jurisdiction to investigate or prosecute violations of criminal law. "Law enforcement" includes, but is not limited to, such agencies as police departments, United States attorneys, the DEA, county attorneys, and the Medicaid fraud control unit.

"Licensing authority" means an agency that licenses or registers health care professionals and has jurisdiction to enforce governing laws over those individuals who are licensed or registered. "Licensing authority" includes, but is not limited to, professional licensing boards and the DEA.

"NarxCare" means an analytics tool and care management platform that helps practitioners analyze real-time data from the PMP. The platform analyzes patient data and history to provide a patient risk score and usage patterns to help practitioners identify potential risk factors.

"NDC number" means the universal product identifier used in the United States to identify a specific human drug.

"Opioid antagonist" means a drug that binds to opioid receptors and blocks or inhibits the effects of opioids acting on those receptors, including but not limited to naloxone hydrochloride or any other similarly acting drug approved by the United States Food and Drug Administration.

"Patient" means a person or animal to whom a prescription is prescribed or dispensed.

"PMP administrator" means staff persons designated to manage and administer the PMP under the direction and oversight of the board and the council.

"Practitioner" means a prescriber or a pharmacist.

"Practitioner's delegate" means a health care professional who is under the supervision of a PMP-registered practitioner and who is authorized by the practitioner to access PMP information on the practitioner's behalf.

"Prescriber" means an individual with an active CSA registration who has the authority to prescribe controlled substances. For the purposes of this chapter, "prescriber" does not include a licensed veterinarian.

"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.

"Reportable prescription" means the record of a controlled substance administered or dispensed by a practitioner and the record of an opioid antagonist dispensed by a practitioner or administered by a first responder. "Reportable prescription" shall not include records identified in subrule 37.7(1). "Reportable prescription" shall include, but not be limited to:

1. The dispensing of a controlled substance to an emergency department patient;
2. The administration of a controlled substance to a patient at the discretion of the treating practitioner
3. The administration or dispensing of an opioid antagonist to an emergency department patient;
4. The dispensing of a controlled substance sample;
5. The dispensing of a controlled substance or opioid antagonist to a patient upon discharge from a hospital or care facility; and
6. The dispensing of a Schedule V controlled substance without a prescription pursuant to rule 657—10.33(124,155A).

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19; **ARC 5545C**, IAB 4/7/21, effective 5/12/21]

657—37.3(124) Registration. Registration for the PMP pursuant to this rule shall be via the Iowa PMP AWARxE website at iowa.pmpaware.net.

37.3(1) *Prescribers.* A prescriber shall register for the PMP at the same time the prescriber registers or renews a CSA registration pursuant to 657—Chapter 10. A licensed veterinarian with an active CSA registration may register for the PMP. Registration for the PMP shall also require the prescriber's DEA number.

37.3(2) *Pharmacists.* A pharmacist who is involved in patient care shall register for the PMP at the same time the pharmacist becomes licensed or renews a license pursuant to 657—Chapter 2.

37.3(3) *Practitioner's delegates.* A practitioner may authorize an adequate number of health care professionals who actively work with the practitioner to act as the practitioner's delegates for the purpose of requesting PMP information. A practitioner's delegate shall be licensed, registered, certified, or otherwise credentialed as a health care professional in a manner that permits verification of the health

care professional's credentials. The practitioner shall be responsible for the PMP information access of the practitioner's delegates.

37.3(4) *Law enforcement officials.* A law enforcement official may register for the PMP to access information by order, subpoena, or other means of legal compulsion relating to a specific investigation and supported by a determination of probable cause.

37.3(5) *Licensing authority.* A licensing authority official may register for the PMP to access information by order, subpoena, or other means of legal compulsion relating to a specific investigation and supported by a determination of probable cause.

37.3(6) *Medical examiners and medical examiner investigators.* A medical examiner or a medical examiner investigator may register for the PMP to access information when the information relates to an investigation being conducted by the examiner or investigator.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.4 and **37.5** Reserved.

657—37.6(124) Security of PMP credentials. Each user registered to access PMP information shall securely maintain and use the login and password and any other secure access credentials assigned to the individual user. Except in an emergency when a patient would be placed in greater jeopardy by restricting PMP information access to the user, a registered user shall not share the user's secure access credentials.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.7(124) PMP reporting—exemptions.

37.7(1) *Exempted dispensing or administration.* The dispensing or administration of a controlled substance as described in this subrule shall not be considered a reportable prescription. A pharmacy engaged in the distribution of controlled substances solely pursuant to one or more of the practices identified in this subrule shall notify the PMP administrator of the exempted practice, and the pharmacy shall not be required to report to the PMP.

a. The dispensing by a licensed hospital pharmacy for the purposes of inpatient hospital care.

b. The dispensing by a licensed pharmacy for a patient residing in a health care facility or inpatient hospice facility.

c. The administration by a prescriber of a controlled substance for the purposes of outpatient procedures and treatment.

d. The sale by a licensed pharmacy of a Schedule V controlled substance without a prescription which sale is subject to the reporting requirements of 657—Chapter 100.

37.7(2) *Exempted practitioners.* The following entities or individuals shall not be required to report to the PMP and shall not be required to notify the PMP administrator of their exempted status:

a. A licensed pharmacy that does not have a CSA registration and does not dispense controlled substances in or into Iowa.

b. A licensed veterinarian who administers or dispenses a controlled substance in the normal course of the veterinarian's professional practice.

c. A DEA-registered narcotic treatment program which is subject to the record-keeping provisions of 21 CFR Section 1304.24.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19; **ARC 5545C**, IAB 4/7/21, effective 5/12/21]

657—37.8(124) PMP reporting—dispensing prescribers. Each dispensing prescriber, unless exempt pursuant to rule 657—37.7(124), shall submit to the PMP a record of each reportable prescription dispensed during a reporting period pursuant to subrule 37.12(2). For purposes of prescriber dispensing, the prescriber shall also be identified as the dispenser or pharmacy. A veterinarian may, but shall not be required to, submit to the PMP a record of reportable prescriptions dispensed by the veterinarian.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19; **ARC 5545C**, IAB 4/7/21, effective 5/12/21]

657—37.9(124) PMP reporting—pharmacies. Each pharmacy, unless exempt pursuant to rule 657—37.7(124), shall submit to the PMP either a record of each reportable prescription dispensed or

administered during a reporting period pursuant to subrule 37.12(2) or a zero report pursuant to subrule 37.12(4), as appropriate.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.10 and **37.11** Reserved.

657—37.12(124) Reporting requirements.

37.12(1) *Data elements.* The information submitted to the PMP for each reportable prescription shall be accurate and shall include, at a minimum, the following data elements:

a. Dispenser DEA number.
b. Date the prescription is dispensed or administered.
c. Prescription number or unique identification number.
d. NDC number of the drug dispensed or administered.
e. Quantity of the drug dispensed or administered.
f. Number of days of drug therapy provided by the drug dispensed or administered.
g. Patient legal first and last names.
h. Patient address including street address, city, state, and ZIP code.
i. Patient phone number.
j. Patient date of birth.
k. Patient gender.
l. Prescriber name and DEA number.
m. Date the prescription was issued by the prescriber.
n. Method of payment.
o. Form of transmission of prescription origin.
p. Refill number.
q. Number of refills authorized.
r. Indication as to whether the prescription is new or a refill.

37.12(2) *Reporting periods.* A record of each reportable administration or prescription dispensed shall be submitted by each dispenser no later than the next business day following administration or dispensing.

37.12(3) *Transmission.* Prescription dispensing and administration information shall be transmitted via the PMP's current version of data upload or electronic submission.

37.12(4) *Zero reports.* If a pharmacy did not dispense or administer any reportable prescriptions during a reporting period, the dispenser shall submit a zero report no later than the next business day.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.13(124) Opioid antagonist administration by first responders.

37.13(1) The administration of an opioid antagonist by a first responder shall be reported to the PMP, unless such administration was reported to the Iowa department of public health bureau of emergency and trauma services.

37.13(2) The reporting of the administration of an opioid antagonist by a first responder shall include the following data elements:

a. Patient first and last names.
b. First and last names of the individual who administered the opioid antagonist.
c. Date of administration.
d. Quantity of the opioid antagonist administered.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.14 and **37.15** Reserved.

657—37.16(124) Access to PMP information. All information contained in the PMP is confidential and shall only be accessed as provided in this rule. All requests for PMP information must comply with the format specified by the board for the particular type of request. Once information is accessed, further

dissemination or use of that information is governed by applicable federal and state laws governing the person who accessed the information. The board may charge a fee to recover the actual costs associated with responding to any request by a person other than a practitioner or a practitioner's delegate. Any fees or costs assessed by the board shall be considered repayment receipts as defined in Iowa Code section 8.2.

37.16(1) *Prescribers.* A prescriber may access a patient's prescription history report; the prescriber's activity report; proactive alerts or system user notes, such as peer-to-peer communication; and NarxCare reports. A veterinarian with authority to prescribe controlled substances may access a current patient's or client's prescription history report if the veterinarian has a reasonable basis to suspect the client may be abusing drugs or mistreating an animal.

37.16(2) *Pharmacists.*

a. A pharmacist may access a patient's or client's prescription history report; proactive alerts or system user notes, such as peer-to-peer communication; and NarxCare reports.

b. A pharmacist shall review a patient's or client's prescription history report prior to dispensing a Schedule V controlled substance without a prescription pursuant to rule 657—10.33(124,155A).

37.16(3) *Practitioner's delegates.* A practitioner's delegate may access a patient's prescription history report; proactive alerts or system user notes, such as peer-to-peer communication; and NarxCare reports.

37.16(4) *Licensing authority officials.*

a. A licensing authority with jurisdiction over a practitioner may obtain the following information, if the request is accompanied by a subpoena compelling disclosure of such information for a specific investigation into the prescribing or dispensing practices of the licensee: prescription history reports; proactive alerts or system user notes, such as peer-to-peer communication; PMP access logs and login records; and NarxCare reports.

b. A licensing authority with jurisdiction over a health care professional may obtain the following information, if the request is accompanied by a subpoena compelling disclosure of such information for a specific investigation into the licensee's misuse of controlled substances: the licensee's prescription history report.

37.16(5) *Law enforcement officials.* A law enforcement official may obtain a patient's prescription history report and the prescribing or dispensing practices of a prescriber if the request is accompanied by a subpoena or other means of legal compulsion compelling disclosure of such information for use in a specific investigation.

37.16(6) *Medical examiners and medical examiner investigators.* A medical examiner or medical examiner investigator may obtain a decedent's prescription history report for use in a specific investigation.

37.16(7) *Patients.* A patient or the patient's agent may request the patient's own prescription history report by using the board's patient request form. The request can be personally delivered to the board office where the patient will be required to present current government-issued photo identification at the time of the delivery of the request. A patient who is unable to personally deliver the request to the board office may submit a notarized request, along with a certified copy of the patient's government-issued photo identification, via mail or commercial delivery service. The following agents may submit a request on behalf of a patient: an individual with a medical power of attorney for the patient, a patient's attorney, or an executor of the patient's estate. 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 copy of the legal document that establishes the agency relationship with the patient.

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19; **ARC 5545C**, IAB 4/7/21, effective 5/12/21]

657—37.17(124) Integrated systems. A practitioner or a health care system may integrate its electronic health record system or a pharmacy may integrate its automated data processing system with the PMP

using an application programming interface. Use of an integrated system shall comply with all of the following:

37.17(1) The integrated system shall log each user's access to PMP information. Access logs shall be retained by the practitioner, health care system, or pharmacy for a minimum of four years from the date of access and shall be provided to the board upon request.

37.17(2) If the user identified in access logs is not the practitioner, the integrated system shall clearly identify on which practitioner's behalf the user was accessing PMP information. A practitioner's delegate using an integrated system is required to maintain active PMP registration.

37.17(3) The integrated system shall maintain appropriate administrative, technical, and physical security measures to safeguard against unauthorized access, disclosure, or theft of PMP information and shall meet all HIPAA requirements for safeguarding protected health information.

37.17(4) The practitioner, health care system, or pharmacy shall notify the PMP administrator of any breach in the electronic health record system that may have included PMP information within 72 hours of making the determination that a breach occurred.

37.17(5) An integrated system shall comply with all requirements in subchapter VI of Iowa Code chapter 124 and all requirements of this chapter.

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.18(124) PMP administrator access.

37.18(1) *PMP staff.* The board may designate PMP administrators who may access any PMP information needed to perform the functions of the job.

37.18(2) *Statistical data.* The PMP administrator or designee may provide summary, statistical, or aggregate data to public or private entities for statistical, public research, public policy, or educational purposes. The board may charge a fee to recover the actual costs associated with responding to a request for PMP data pursuant to this subrule. Any fees or costs assessed by the board shall be considered repayment receipts as defined in Iowa Code section 8.2.

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.19(124) Prescriber activity reports. The PMP administrator shall, at least annually, electronically issue to each prescriber who prescribed a controlled substance that was reported to the program as dispensed in or into this state during the preceding reporting period an activity report which shall include, at a minimum, the following:

1. A summary of the prescriber's history of prescribing controlled substances,
2. A comparison of the prescriber's history of prescribing controlled substances with the history of other prescribers of the same profession or specialty,
3. The prescriber's history of program use,
4. General patient risk factors, and
5. Educational updates.

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.20(124) Proactive notifications. The PMP administrator shall provide notification to a practitioner when a patient may be practitioner shopping or at risk of abusing or misusing a controlled substance based on criteria and thresholds determined by the board and the advisory council. A proactive notification pursuant to this rule will be initiated when a patient obtains prescriptions for controlled substances from a minimum number of prescribing practitioners and from a minimum number of pharmacies within a maximum number of days which exceed the thresholds established by the board and advisory council. The notification will suggest review of the patient's prescription history.

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.21(124) Record retention. The PMP shall retain all reported prescriptions, all records of access to or query of PMP information, and all information distributed to practitioners in proactive notifications for a minimum of four years from the date of the record.

[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.22(124) Information errors. Any person who believes that PMP information is erroneous shall notify the pharmacy or dispensing practitioner. Upon notification of a potential error in PMP information, the pharmacy or dispensing practitioner shall promptly correct erroneous information in the record.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

657—37.23(124) Discipline. Any licensee who fails to comply with the provisions of the law or these rules is subject to disciplinary action by the board and may be subject to criminal prosecution.
[**ARC 4397C**, IAB 4/10/19, effective 5/15/19]

These rules are intended to implement Iowa Code sections 124.550 to 124.558.

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CHAPTER 38
Reserved

CHAPTER 39
EXPANDED PRACTICE STANDARDS

657—39.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standards for the programs and activities identified in this chapter. These rules shall apply to all licensed pharmacists, other registered pharmacy personnel, and all pharmacies, including owners, engaged in the state of Iowa in the programs and activities identified in this chapter. These rules are in addition to rules of the board relating to the practice of pharmacy unless otherwise indicated by rule.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.2 and **39.3** Reserved.

657—39.4(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 prescriber.

39.4(1) *Drug therapy problems.* In providing pharmaceutical care, the pharmacist shall strive to identify, resolve, and prevent drug therapy problems.

39.4(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 drug therapy plan as appropriate.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.5 Reserved.

657—39.6(155A) Statewide protocols. A pharmacist may, pursuant to statewide protocols developed by the board in consultation with the department of public health and available on the board's website at pharmacy.iowa.gov, order and dispense medications pursuant to rules 657—39.8(155A), 657—39.9(155A), and 657—39.11(155A). For the purpose of this rule, the order shall constitute a prescription.
[**ARC 4270C**, IAB 1/30/19, effective 3/6/19; see Delay note at end of chapter; **ARC 4387C**, IAB 4/10/19, effective 4/5/19; **ARC 4583C**, IAB 7/31/19, effective 9/4/19]

657—39.7(135,147A) Opioid antagonist dispensing by pharmacist—standing order. An authorized pharmacist may dispense an opioid antagonist pursuant to a standing order established by the department, which standing order can be found via the board's website, or pursuant to a standing order authorized by an individual licensed health care professional in compliance with the requirements of this rule. An authorized pharmacist may only delegate the dispensing of an opioid antagonist to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist. Nothing in this rule prohibits a prescriber or facility from establishing and implementing standing orders or protocols under the authority granted to the prescriber or facility.

39.7(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Authorized pharmacist" means an Iowa-licensed pharmacist who has completed the training requirements of this rule. "Authorized pharmacist" also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct supervision of an authorized Iowa-licensed pharmacist.

"Department" means the Iowa department of public health.

"First responder" means an emergency medical care provider, a registered nurse staffing an authorized service program under Iowa Code section 147A.12, a physician assistant staffing an

authorized service program under Iowa Code section 147A.13, a firefighter, or a peace officer as defined in Iowa Code section 801.4 who is trained and authorized to administer an opioid antagonist.

"Licensed health care professional" means a person licensed under Iowa Code chapter 148 to practice medicine and surgery or osteopathic medicine and surgery, an advanced registered nurse practitioner licensed under Iowa Code chapter 152 or 152E and registered with the board of nursing, or a physician assistant licensed to practice under the supervision of a physician as authorized in Iowa Code chapters 147 and 148C.

"Opioid antagonist" means the same as defined in Iowa Code section 147A.1.

"Opioid-related overdose" means the same as defined in Iowa Code section 147A.1.

"Person in a position to assist" means a family member, friend, caregiver, health care provider, employee of a substance abuse treatment facility, or other person who may be in a position to render aid to a person at risk of experiencing an opioid-related overdose.

"Recipient" means an individual at risk of an opioid-related overdose or a person in a position to assist an individual at risk of an opioid-related overdose.

"Standing order" means a preauthorized medication order with specific instructions from the licensed health care professional to dispense a medication under clearly defined circumstances.

39.7(2) *Authorized pharmacist training.* An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to opioid antagonist utilization prior to dispensing opioid antagonists pursuant to a standing order.

39.7(3) *Additional supply.* Notwithstanding a standing order to the contrary, an authorized pharmacist shall only dispense an opioid antagonist after completing an eligibility assessment and providing training and education to the recipient.

39.7(4) *Assessment.* An authorized pharmacist shall assess an individual for eligibility to receive an opioid antagonist pursuant to a standing order. In addition to the criteria identified in a standing order, an authorized pharmacist shall also take into consideration the following criteria to determine the eligibility of the recipient to receive and possess an opioid antagonist:

a. The person at risk of an opioid-related overdose for which the opioid antagonist is intended to be administered has no known sensitivity or allergy to naloxone, unless the person at risk is not known to the recipient, including but not limited to a first responder or member of law enforcement.

b. The recipient is oriented to person, place, and time and able to understand and learn the essential components of opioid-related overdose, appropriate response, and opioid antagonist administration.

39.7(5) *Recipient training and education.* Upon assessment and determination that an individual is eligible to receive and possess an opioid antagonist pursuant to a standing order, an authorized pharmacist shall, prior to dispensing an opioid antagonist pursuant to a standing order, provide training and education to the recipient including, but not limited to, the information identified in this subrule. An authorized pharmacist shall require the recipient to attest that, if the product will be accessible to any other individual for administration, the recipient will make available to such individual all received training and education materials. An authorized pharmacist may provide to the recipient written materials that include, but may not be limited to, the information identified in this subrule, but the written materials shall not be in lieu of direct pharmacist consultation with the recipient.

a. The signs and symptoms of opioid-related overdose as described in the standing order.

b. The importance of calling 911 as soon as possible and the potential need for rescue breathing.

c. The appropriate use and directions for administration of the opioid antagonist to be dispensed pursuant to the standing order.

d. Adverse reactions of the opioid antagonist as well as reactions resulting from opioid withdrawal following administration.

e. The proper storage conditions, including temperature excursions, of the opioid antagonist being dispensed.

f. The expiration date of the opioid antagonist being dispensed and the appropriate disposal of the opioid antagonist upon expiration.

g. The prohibition of the recipient from further distributing the opioid antagonist to another individual, unless that individual has received appropriate training and education.

h. Information about substance abuse or behavioral health treatment programs.

39.7(6) *Labeling.* Upon the determination that a recipient is eligible to receive and possess an opioid antagonist, an authorized pharmacist shall label the product pursuant to rule 657—6.10(126,155A) and 657—subrule 8.19(8). An authorized pharmacist shall ensure that the labeling does not render the expiration date of the product illegible. The medication shall be dispensed in the name of the eligible recipient.

39.7(7) *Reporting.* A copy of the assessment form shall be submitted to the department as provided on the assessment form within seven days of the dispensing of the opioid antagonist or within seven days of a denial of eligibility.

39.7(8) *Records.* An authorized pharmacist shall create and maintain an original record of each individual assessment on forms provided by the board, regardless of the eligibility determination following assessment, and dispensing of opioid antagonists pursuant to a standing order. These records shall be available for inspection and copying by the board or its authorized agent for at least two years.
[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.8(155A) Statewide protocol—naloxone. An authorized pharmacist may order and dispense naloxone to patients 18 years and older pursuant to a statewide protocol developed pursuant to rule 657—39.6(155A) and in compliance with this rule. An authorized pharmacist may only delegate the dispensing of naloxone to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist. For the purpose of this rule, the order shall constitute a prescription.

39.8(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Authorized pharmacist" means an Iowa-licensed pharmacist who has completed the training requirements of this rule. "Authorized pharmacist" also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct supervision of an authorized pharmacist.

"Authorized pharmacist-intern" means an Iowa-registered pharmacist-intern who has completed the training requirements for an authorized pharmacist pursuant to this rule.

"Board" means the Iowa board of pharmacy.

"Patient" means an individual consulting with a pharmacist for drug therapy and may include an individual in a position to assist someone at risk of an opioid-related overdose.

39.8(2) *Authorized pharmacist training.* An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to naloxone utilization prior to dispensing naloxone pursuant to the statewide protocol.

39.8(3) *Assessment.* An authorized pharmacist shall assess a patient for eligibility to receive naloxone using criteria identified in the statewide protocol.

39.8(4) *Patient education.* Upon assessment and determination that a patient is eligible to receive and possess naloxone pursuant to the statewide protocol, an authorized pharmacist shall, prior to dispensing naloxone pursuant to the statewide protocol, provide training and education to the patient including, but not limited to, the information identified in this subrule. An authorized pharmacist may provide to the patient written materials that include, but may not be limited to, the information identified in this subrule, but the written materials shall not be in lieu of direct pharmacist consultation with the patient.

a. The signs and symptoms of opioid-related overdose as described in the statewide protocol.

b. The importance of calling 911 as soon as possible and the potential need for rescue breathing.

c. The appropriate use and directions for administration of the naloxone to be dispensed pursuant to the statewide protocol.

d. Adverse reactions of naloxone as well as reactions resulting from opioid withdrawal following administration.

e. The proper storage conditions, including temperature excursions, of the naloxone product being dispensed.

f. The expiration date of the naloxone product being dispensed and the appropriate disposal of the naloxone product upon expiration.

g. Information about substance abuse or behavioral health treatment programs, if applicable.

39.8(5) *Labeling.* Naloxone dispensed pursuant to this rule shall be labeled in accordance with rule 657—6.10(126,155A), and the labeling shall not render the expiration date of the product illegible.

39.8(6) *Reporting.* As soon as reasonably possible, the authorized pharmacist shall notify the patient's primary health care provider of the naloxone product provided to the patient. If the patient does not have a primary health care provider, the authorized pharmacist shall provide the patient with a written record of the naloxone product provided to the patient and shall advise the patient to consult a physician.

39.8(7) *Records.* An authorized pharmacist shall maintain records of naloxone ordered and dispensed pursuant to the statewide protocol.

[**ARC 4270C**, IAB 1/30/19, effective 3/6/19; see Delay note at end of chapter; **ARC 4387C**, IAB 4/10/19, effective 4/5/19; **ARC 4583C**, IAB 7/31/19, effective 9/4/19]

657—39.9(155A) Statewide protocol—nicotine replacement tobacco cessation products. An authorized pharmacist may order and dispense nicotine replacement tobacco cessation products to patients 18 years and older pursuant to a statewide protocol developed pursuant to rule 657—39.6(155A) and in compliance with this rule. An authorized pharmacist may only delegate the dispensing of a nicotine replacement tobacco cessation product to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist. For the purpose of this rule, the order shall constitute a prescription.

39.9(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Authorized pharmacist" means an Iowa-licensed pharmacist who has completed the training requirements of this rule. "Authorized pharmacist" also includes an Iowa-registered pharmacist-intern who has completed the training requirements of this rule and is working under the direct supervision of an authorized pharmacist.

"Authorized pharmacist-intern" means an Iowa-registered pharmacist-intern who has completed the training requirements for an authorized pharmacist pursuant to this rule.

"Board" means the Iowa board of pharmacy.

39.9(2) *Authorized pharmacist training.* An authorized pharmacist shall document successful completion of an ACPE-approved continuing education program of at least one-hour duration related to nicotine replacement tobacco cessation product utilization prior to dispensing such products under the statewide protocol.

39.9(3) *Assessment.* An authorized pharmacist shall assess a patient for appropriateness of receiving a nicotine replacement tobacco cessation product pursuant to the statewide protocol.

39.9(4) *Patient counseling and instructions.* Upon assessment and determination that provision of the nicotine replacement tobacco cessation product is appropriate pursuant to the statewide protocol, an authorized pharmacist shall, prior to dispensing such product, provide counseling and instructions to the patient pursuant to rule 657—6.14(155A).

39.9(5) *Labeling.* Nicotine replacement tobacco cessation products dispensed pursuant to this rule shall be labeled in accordance with rule 657—6.10(126,155A), and the labeling shall not render the expiration date of the product illegible.

39.9(6) *Reporting.* As soon as reasonably possible, the authorized pharmacist shall notify the patient's primary health care provider of the nicotine replacement tobacco cessation product provided to the patient. If the patient does not have a primary health care provider, the authorized pharmacist shall provide the patient with a written record of the nicotine replacement tobacco cessation product provided to the patient and shall advise the patient to consult a physician.

39.9(7) *Records.* An authorized pharmacist shall maintain records of nicotine replacement tobacco cessation products ordered and dispensed pursuant to the statewide protocol.

[**ARC 4270C**, IAB 1/30/19, effective 3/6/19; see Delay note at end of chapter; **ARC 4387C**, IAB 4/10/19, effective 4/5/19; **ARC 4583C**, IAB 7/31/19, effective 9/4/19]

657—39.10(155A) Vaccine administration by pharmacists—physician-approved protocol. Through June 30, 2021, an authorized pharmacist may administer vaccines pursuant to protocols established by the CDC in compliance with the requirements of this rule. An authorized pharmacist may only delegate the administration of a vaccine to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

39.10(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"ACIP" means the CDC Advisory Committee on Immunization Practices.

"ACPE" means the Accreditation Council for Pharmacy Education.

"Authorized pharmacist" means an Iowa-licensed pharmacist who has met the requirements identified in subrule 39.10(2).

"Authorized pharmacist-intern" means an Iowa-registered pharmacist-intern who has met the requirements for an authorized pharmacist identified in paragraphs 39.10(2)*"a"* and *"c."*

"CDC" means the United States Centers for Disease Control and Prevention.

"Immunization" shall have the same meaning as, and shall be interchangeable with, the term "vaccine."

"Protocol" means a standing order for a vaccine to be administered by an authorized pharmacist.

"Vaccine" means a specially prepared antigen administered to a person for the purpose of providing immunity.

39.10(2) *Authorized pharmacist training and continuing education.* An authorized pharmacist shall document successful completion of the requirements in paragraph 39.10(2)*"a"* and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 39.10(2)*"b."*

a. Initial qualification. An authorized pharmacist shall have successfully completed an organized course of study in a college or school of pharmacy or an ACPE-accredited continuing education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

(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 CDC 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, counseling, and identification of contraindications to the vaccine;
9. Immunization record management; and
10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

b. Continuing education. During any pharmacist license renewal period, an authorized pharmacist who engages in the administration of vaccines shall complete and document at least one hour of ACPE-approved continuing education with the ACPE topic designator "06" followed by the letter "P."

c. Certification maintained. During any period within which the pharmacist may engage in the administration of vaccines, the pharmacist shall maintain current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

39.10(3) *Protocol requirements.* A pharmacist may administer vaccines pursuant to a protocol based on CDC recommendations. A protocol shall be unique to a pharmacy. The pharmacy shall comply with the parameters of the protocol. The prescriber who signs a protocol shall identify within the protocol,

by name or category, those pharmacists or other qualified health professionals that the prescriber is authorizing to administer vaccines pursuant to the protocol. A protocol:

a. Shall be signed by an Iowa-licensed prescriber practicing in Iowa.

b. Shall expire no later than one year from the effective date of the signed protocol.

c. Shall be effective for patients who wish to receive a vaccine administered by an authorized pharmacist, who meet the CDC recommended criteria, and who have no contraindications as published by the CDC.

d. Shall require the authorized pharmacist to notify the prescriber who signed the protocol within 24 hours of a serious complication, and the pharmacist shall submit a Vaccine Advisory Event Reporting System (VAERS) report.

e. Shall specifically indicate whether the authorizing prescriber agrees that the administration of vaccines may be delegated by the authorized pharmacist to an authorized pharmacist-intern under the direct supervision of the authorized pharmacist.

39.10(4) *Influenza and other emergency vaccines.* An authorized pharmacist shall only administer via protocol, to patients six years of age and older, influenza vaccines and other emergency vaccines in response to a public health emergency.

39.10(5) *Other adult vaccines.* An authorized pharmacist shall only administer via protocol, to patients 18 years of age and older, the following vaccines:

a. A vaccine on the ACIP-approved adult vaccination schedule.

b. A vaccine recommended by the CDC for international travel.

39.10(6) *Vaccines administered via prescription.* An authorized pharmacist may administer any vaccine pursuant to a prescription or medication order for an individual patient. In case of a serious complication, the authorized pharmacist shall notify the prescriber who authorized the prescription within 24 hours and shall submit a VAERS report.

39.10(7) *Verification and reporting.* The requirements of this subrule do not apply to influenza and other emergency vaccines administered via protocol pursuant to subrule 39.10(4). An authorized pharmacist shall:

a. Prior to administering a vaccine identified in subrule 39.10(5) or 39.10(6), consult the statewide immunization registry or health information network.

b. As soon as reasonably possible following administration of a vaccine identified in subrule 39.10(5) or 39.10(6), report the vaccine administration to the statewide immunization registry or health information network and to the patient's primary health care provider, if known.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18; **ARC 4270C**, IAB 1/30/19, effective 3/6/19; see Delay note at end of chapter; **ARC 4555C**, IAB 7/17/19, effective 7/1/19; **ARC 5348C**, IAB 12/30/20, effective 2/3/21]

657—39.11(155A) Vaccine administration by pharmacists—statewide protocol. An authorized pharmacist may order and administer vaccines and immunizations pursuant to a statewide protocol developed pursuant to rule 657—39.6(155A) and in compliance with this rule. An authorized pharmacist may only delegate the ordering and administration of a vaccine to an authorized pharmacist-intern under the direct supervision of an authorized pharmacist. For the purpose of this rule, the order shall constitute a prescription.

39.11(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"ACIP" means the CDC Advisory Committee on Immunization Practices.

"ACPE" means the Accreditation Council for Pharmacy Education.

"Authorized pharmacist" means an Iowa-licensed pharmacist who has met the requirements identified in subrule 39.11(3).

"Authorized pharmacist-intern" means an Iowa-registered pharmacist-intern who has met the requirements for an authorized pharmacist identified in subrule 39.11(3).

"Board" means the Iowa board of pharmacy.

"CDC" means the United States Centers for Disease Control and Prevention.

"Immunization" shall have the same meaning as, and shall be interchangeable with, the term "vaccine."

"Vaccine" means a specially prepared antigen administered to a person for the purpose of providing immunity.

39.11(2) *Vaccines authorized by statewide protocol.* The vaccines authorized to be ordered and administered pursuant to the statewide protocol shall include:

a. To patients ages 18 years and older:

(1) An immunization or vaccination recommended by ACIP in its approved vaccination schedule for adults.

(2) An immunization or vaccination recommended by CDC for international travel.

(3) A Tdap (tetanus, diphtheria, acellular pertussis) vaccination in a booster application.

(4) Other emergency immunizations or vaccinations in response to a public health emergency.

b. To patients ages six months and older:

(1) A vaccine or immunization for influenza.

(2) Other emergency immunizations or vaccines in response to a public health emergency.

c. To patients ages 11 years and older:

(1) The final two doses in a course of vaccinations for human papillomavirus (HPV).

(2) Reserved.

39.11(3) *Authorized pharmacist training and continuing education.* An authorized pharmacist shall document successful completion of the requirements in paragraph 39.11(3)*"a"* and shall maintain competency by completing and maintaining documentation of the continuing education requirements in paragraph 39.11(3)*"b."*

a. Initial qualification. An authorized pharmacist shall have successfully completed an organized course of study in a college or school of pharmacy or an ACPE-accredited continuing education program on vaccine administration that:

(1) Requires documentation by the pharmacist of current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

(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 CDC 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, counseling, and identification of contraindications to the vaccine;
9. Immunization record management; and
10. Management of adverse events, including identification, appropriate response, documentation, and reporting.

b. Continuing education. During any pharmacist license renewal period, an authorized pharmacist who engages in the administration of vaccines shall complete and document at least one hour of ACPE-approved continuing education with the ACPE topic designator "06" followed by the letter "P."

c. Certification maintained. During any period within which the pharmacist may engage in the administration of vaccines, the pharmacist shall maintain current certification in basic cardiac life support through a training program designated for health care providers that includes hands-on training.

39.11(4) *Assessment.* An authorized pharmacist shall assess a patient for appropriateness of receiving a vaccine pursuant to the statewide protocol.

39.11(5) *Verification and reporting.* Prior to the ordering and administration of an immunization pursuant to the statewide protocol, the authorized pharmacist shall consult and review the statewide immunization registry or health information network. As soon as reasonably possible following

administration of a vaccine, the pharmacist shall report such administration to the patient's primary health care provider, primary physician, and a statewide immunization registry or health information network. If the patient does not have a primary health care provider, the pharmacist shall provide the patient with a written record of the vaccine administered to the patient and shall advise the patient to consult a physician.

[**ARC 4270C**, IAB 1/30/19, effective 3/6/19; see Delay note at end of chapter; **ARC 4387C**, IAB 4/10/19, effective 4/5/19; **ARC 4583C**, IAB 7/31/19, effective 9/4/19]

657—39.12 Reserved.

657—39.13(155A) Collaborative drug therapy management. An authorized pharmacist may only perform collaborative drug therapy management pursuant to protocol with an authorized provider pursuant to the requirements of this rule. The authorized provider 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.

39.13(1) *Definitions.* For the purpose of this rule, the following definitions shall apply:

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

"Authorized provider" means an Iowa-licensed prescribing practitioner who is authorized by the practitioner's professional licensing authority to participate in a collaborative practice agreement with an authorized pharmacist pursuant to these rules and the rules of the practitioner's professional licensing authority. An authorized provider 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 authorized provider may delegate only drug therapies that are in areas common to the authorized provider's practice.

"Board" means the board of pharmacy.

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

"Collaborative practice" means that an authorized provider may delegate aspects of drug therapy management for the authorized provider'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 an authorized provider establishing drug therapy management for one or more of the pharmacist's and authorized provider's patients residing in a community setting. A community practice protocol shall comply with the requirements of subrule 39.13(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 authorized providers 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 authorized providers at a hospital or the hospital's clinics or only to those pharmacists and authorized providers who are specifically recognized. A hospital practice protocol shall comply with the requirements of subrule 39.13(3).

"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.

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

39.13(2) *Community practice protocol.*

a. An authorized pharmacist shall engage in collaborative drug therapy management with an authorized provider only under a written protocol that has been identified by topic. Protocols shall be made available upon request of the board or the licensing board of the authorized provider.

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 authorized provider who may prescribe drugs and is responsible for supervising a patient's drug therapy management. The authorized provider 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 authorized provider.

(3) The name and contact information of the principal authorized provider 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 authorized provider. 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 authorized provider 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 authorized provider, the authorized pharmacist shall secure such and notify the patient's authorized provider within 24 hours.

(6) Circumstances that shall cause the authorized pharmacist to initiate communication with the authorized provider 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 authorized provider.

(10) A description of the types of reports the authorized pharmacist is to provide to the authorized provider 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 authorized provider.

(11) A statement of the medication categories and the type of initiation and modification of drug therapy that the provider 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 an authorized provider from delegating collaborative drug therapy management to any unlicensed or licensed person other than another authorized provider or an authorized pharmacist.

(17) A description of the mechanism for the pharmacist and the authorized provider 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 authorized provider.

d. The collaborative drug therapy protocol shall be kept on file in the pharmacy and be made available upon request of the board or the authorized provider's licensing board.

e. An authorized provider may terminate or amend the collaborative drug therapy management protocol with an authorized pharmacist if the authorized provider notifies the authorized pharmacist in writing. Notification shall include the name of the authorized pharmacist, the desired change, and the proposed effective date of the change. Written notification shall be maintained in the pharmacy and be made available upon request of the board or the authorized provider's licensing board.

f. The authorized provider or pharmacist who initiates a protocol with a patient is responsible for securing the 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 authorized provider shall maintain the patient consent in the patient's medical record.

39.13(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 providers 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 authorized provider. 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 authorized provider for follow-up.

(4) Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's authorized provider 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 authorized provider to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

657—39.14 and **39.15** Reserved.

657—39.16(155A) Pharmacy pilot or demonstration research projects. The purpose of this rule is to specify the procedures to be followed in applying for approval of a pilot or demonstration research project for innovative applications in the practice of pharmacy as authorized by 2011 Iowa Acts, chapter 63, section 36, as amended by 2012 Iowa Acts, chapter 1113, section 31, and by 2013 Iowa Acts, chapter 138, section 128. In reviewing projects, the board will consider only projects that expand pharmaceutical care services that contribute to positive patient outcomes. The board will not consider any project intended only to provide a competitive advantage to a single applicant or group of applicants.

39.16(1) *Definitions.* For the purposes of this rule, the following definitions shall apply:

"Act" means Iowa Code chapter 155A, the Iowa pharmacy practice Act.

"Board" means the Iowa board of pharmacy.

"Practice of pharmacy" means the practice of pharmacy as defined in Iowa Code section 155A.3(37).

"Project" means a pilot or demonstration research project as described in this rule.

39.16(2) *Scope of project.* A project may not expand the definition of the practice of pharmacy. A project may include therapeutic substitution or substitution of medical devices used in patient care if such substitution is included under a collaborative drug therapy management protocol established pursuant to rule 657—39.13(155A).

39.16(3) *Board approval of a project.* Board approval of a project may include the grant of an exception to or a waiver of rules adopted under the Act or under any law relating to the authority of prescription verification and the ability of a pharmacist to provide enhanced patient care in the practice of pharmacy. Project approval, including exception to or waiver of board rules, shall initially be for a specified period of time not exceeding 18 months from commencement of the project. The board may approve the extension or renewal of a project following consideration of a petition that clearly identifies the project, that includes a report similar to the final project report described in paragraph 39.16(6)*"a,"* that describes and explains any proposed changes to the originally approved and implemented project, and that justifies the need for extending or renewing the term of the project.

39.16(4) *Applying for approval of a project.* A person who wishes the board to consider approval of a project shall submit to the board a petition for approval that contains at least the following information:

a. Responsible pharmacist. Name, address, telephone number, and pharmacist license number of each pharmacist responsible for overseeing the project.

b. Location of project. Name, address, and telephone number of each specific location and, if a location is a pharmacy, the pharmacy license number where the proposed project will be conducted.

c. Project summary. A detailed summary of the proposed project that includes at least the following information:

(1) The goals, hypothesis, and objectives of the proposed project.

(2) A full explanation of the project and how it will be conducted.

(3) The time frame for the project including the proposed start date and length of study. The time frame may not exceed 18 months from the proposed start date of the project.

(4) Background information or literature review to support the proposed project.

(5) The rule or rules to be waived in order to complete the project and a request to waive the rule or rules.

(6) Procedures to be used during the project to ensure that the public health and safety are not compromised as a result of the waiver.

39.16(5) *Review and approval or denial of a proposed project.*

a. Staff review. Upon receipt of a petition for approval of a project, board staff shall initially review the petition for completeness and appropriateness. If the petition is incomplete or inappropriate for board consideration, board staff shall return the petition to the requestor with a letter explaining the reason the petition is being returned. A petition that has been returned pursuant to this paragraph may be amended or supplemented as necessary and submitted for reconsideration.

b. Board review. Upon review by the board of a petition for approval of a project, the board shall either approve or deny the petition. If the board approves the petition, the approval:

(1) Shall be specific for the project requested;

(2) Shall approve the project for a specific time period; and

(3) May include conditions or qualifications applicable to the project.

c. Inspection. The project site and project documentation shall be available for inspection and review by the board or its representative at any time during the project review and the approval or denial processes and, if a project is approved, throughout the approved term of the project.

d. Documentation maintained. Project documentation shall be maintained and available for inspection, review, and copying by the board or its representative for at least two years following completion or termination of the project.

39.16(6) *Presentation of reports.* The pharmacist responsible for overseeing a project shall be responsible for submitting to the board any reports required as a condition of a project, including the final project report.

a. Final project report. The final project report shall include a written summary of the results of the project and the conclusions drawn from those results. The final project report shall be submitted to the board within three months after completion or termination of the project.

b. Board review. The board shall receive and review any report regarding the progress of a project and the final project report at a regularly scheduled meeting of the board. The report shall be an item on the open session agenda for the meeting.

[**ARC 3858C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 135.190, 147.76, 147A.18, 155A.2, 155A.3, 155A.13, 155A.33, and 155A.44; and 2011 Iowa Acts, chapter 63, section 36, as amended by 2012 Iowa Acts, chapter 1113, section 31, and by 2013 Iowa Acts, chapter 138, section 128.

[Filed ARC 3858C (Notice ARC 3509C, IAB 12/20/17), IAB 6/20/18, effective 7/25/18]

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[Filed Emergency ARC 4387C, IAB 4/10/19, effective 4/5/19]

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[Filed ARC 5348C (Notice ARC 5113C, IAB 7/29/20), IAB 12/30/20, effective 2/3/21]

[1] March 6, 2019, effective date of ARC 4270C [amendments to ch 39] delayed 70 days by the Administrative Rules Review Committee at its meeting held February 8, 2019; delay lifted at the meeting held April 5, 2019.

CHAPTER 40
TECHNOLOGY-ASSISTED TECHNICIAN PRODUCT VERIFICATION PROGRAMS

657—40.1(155A) Purpose and scope. A pharmacy located in Iowa which provides clinical pharmacy services may, but shall not be required to, develop and implement a technician product verification (TPV) program in accordance with these rules. For the purpose of this chapter, clinical pharmacy services shall mean services that exceed the minimum requirements of the practice of pharmacy. Clinical pharmacy services include, but are not limited to, medication therapy management, collaborative practice, statewide protocols, and immunizations. In a TPV program, certified pharmacy technicians provide technology-assisted final drug product verification during the prescription-filling or medication distribution process. The pharmacist shall still be responsible for verification of the accuracy of data entry, drug utilization review, ensuring rational drug therapy, and counseling. The on-site practice hours for a pharmacist shall not be reduced but shall be redistributed directly to clinical pharmacy services to improve patient care and health outcomes.
[**ARC 4456C**, IAB 5/22/19, effective 6/26/19; Editorial change: IAC Supplement 9/8/21]

657—40.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Board" means the board of pharmacy.

"Certified pharmacy technician" means an individual who holds a valid current national certification and who has registered with the board as a certified pharmacy technician pursuant to 657—Chapter 3.

"Checking technician" means a certified pharmacy technician who has been authorized pursuant to rule 657—40.4(155A) by the responsible pharmacist to provide drug product verification in a TPV program.

"Representative sample" means a subset of prescriptions that must be verified by a pharmacist for each checking technician involved in a TPV program. A subset consists of a minimum of 1 percent of prescriptions verified by each checking technician or 25 prescriptions per checking technician, whichever is greater.

"Responsible pharmacist" means the pharmacist who is designated by the pharmacy or pharmacist in charge to oversee a TPV program and who is responsible for ensuring the TPV program complies with these rules.

"Technician product verification program" or *"TPV"* means a program formally established and implemented pursuant to these rules which permits a checking technician to provide technology-assisted drug product verification during the prescription-filling or medication distribution process. "TPV" includes programs previously approved by the board as "tech-check-tech" or "TCT" programs.
[**ARC 4456C**, IAB 5/22/19, effective 6/26/19]

657—40.3(155A) TPV program requirements.

40.3(1) *Site-specific.* A TPV program shall be specific to the site at which technician product verification is utilized.

40.3(2) *TPV program oversight.* A pharmacy shall, at all times, have one designated responsible pharmacist who is responsible for meeting TPV program requirements. The responsible pharmacist is not required to be on duty at all times when the TPV program is in use and may designate one or more pharmacists on duty to supervise the activities of checking technicians.

40.3(3) *Checking technician qualifications.* Prior to authorizing a technician to conduct TPV program checking technician activities, the responsible pharmacist shall ensure the certified pharmacy technician has met the minimum requirements of rule 657—40.4(155A).

40.3(4) *Staff responsibilities.* Within a TPV program, each pharmacist shall optimize clinical pharmacy services and ensure consistent and safe implementation of the program. A pharmacist shall be on site and available to checking technicians during any period when TPV is utilized. Each individual involved in the TPV program shall be responsible for the activities performed by that individual, ensuring the activities adhere to TPV program policies and procedures and board rules.

40.3(5) *Technology required.* The pharmacy's prescription processing system shall have appropriate scanning technology to ensure each product is accurately filled and verified. Scanning technology shall

include barcode scanning or superior electronic scanning to verify that the National Drug Code (NDC) of the container of product being used to fill the prescription or medication order matches the NDC of the product entered into the pharmacy's prescription processing system to fill the prescription or medication order. Only a pharmacist shall be authorized to override a scanning technology error or exception. When scanning technology does not function properly, only a pharmacist shall be authorized to visually verify the product or manually enter the drug product into the pharmacy's prescription processing system. The pharmacy's prescription processing system shall be capable of documenting each step of the dispensing or medication distribution process and identifying which pharmacy employee was responsible for each step of the dispensing or distribution process.

40.3(6) *Pharmacy responsibility.* Except in an institutional setting, a pharmacy utilizing a TPV program shall ensure that no more than three checking technicians per pharmacist are engaged in TPV activities within the prescription-filling process at any time. The pharmacy shall ensure that on-site pharmacist practice hours are not reduced but are redistributed directly to clinical pharmacy services.

40.3(7) *Board notification and inspection.* Prior to implementing a TPV program, a pharmacy shall provide advance notice to the board, on forms provided by the board, of its intention to implement a TPV program. The board may require an on-site inspection prior to program commencement.

40.3(8) *Program discontinuation.* A pharmacy shall provide notice to the board when it discontinues a TPV program. A pharmacy intending to implement a previously discontinued TPV program shall provide advance notice to the board, on forms provided by the board, of its intent to implement a TPV program pursuant to subrule 40.3(7).

[**ARC 4456C**, IAB 5/22/19, effective 6/26/19; Editorial change: IAC Supplement 9/8/21]

657—40.4(155A) Checking technician requirements. A certified pharmacy technician shall comply with the requirements of this rule prior to being authorized to engage in checking technician activities in a TPV program. Prior to authorizing the technician to engage in TPV activities, the responsible pharmacist shall ensure the technician is proficient in all aspects of the TPV program and the responsibilities of a checking technician.

40.4(1) *Minimum qualifications.*

a. *National certification.* The certified pharmacy technician's national certification as required pursuant to rule 657—3.5(155A) shall be current.

b. *Iowa registration.* The certified pharmacy technician's registration with the board as required pursuant to rule 657—3.3(155A) shall be current and not currently subject to disciplinary charges or sanctions.

c. *Prior experience.* The certified pharmacy technician shall have completed a minimum of 2,000 hours as a technician and be trained pursuant to subrule 40.4(2).

40.4(2) *Training.* Pursuant to the pharmacy's policies and procedures, the technician shall satisfactorily complete a training program prior to being authorized to engage in TPV activities. The elements of the pharmacy's training program shall be described in the advance notice provided to the board pursuant to subrule 40.3(7).

[**ARC 4456C**, IAB 5/22/19, effective 6/26/19]

657—40.5 and **40.6** Reserved.

657—40.7(155A) Policies and procedures. Policies and procedures shall be developed and adhered to in a TPV program. Policies and procedures for a TPV program shall include, at a minimum, the following:

1. A program to train certified pharmacy technicians to be checking technicians pursuant to subrule 40.4(2), including but not limited to training in the scanning technology to be utilized in the TPV program, limitations of the scanning technology, and strategies to compensate for these limitations.

2. A procedure to identify a representative sample to complete a quarterly quality assurance double check of prescriptions verified by each checking technician.

3. Redirection of pharmacist hours to clinical pharmacy services.

4. Identification of drug products for which authorized checking technicians will be prohibited from performing final drug product verification during the prescription-filling or medication distribution process.

[**ARC 4456C**, IAB 5/22/19, effective 6/26/19]

657—40.8(155A) TPV program quality assurance.

40.8(1) *Quality assurance program—quarterly verification.* The responsible pharmacist shall establish and implement a quality assurance program to evaluate TPV program activities. Each quarter, a pharmacist shall verify a representative sample of prescriptions verified by each checking technician. The quarterly verification shall be documented, and such documentation shall be maintained pursuant to subrule 40.11(2).

40.8(2) *Review of errors.* Any error resulting from TPV shall be documented and evaluated via the pharmacy's continuous quality improvement program (CQI) pursuant to rule 657—8.26(155A) and shall require the technician responsible for the error to be retrained through the pharmacy's established training program.

40.8(3) *Quarterly reports.* The responsible pharmacist shall ensure the completion of a quarterly report on forms provided by the board. The quarterly report shall be maintained in the pharmacy pursuant to subrule 40.11(3).

[**ARC 4456C**, IAB 5/22/19, effective 6/26/19]

657—40.9 and **40.10** Reserved.

657—40.11(155A) TPV program records. The records required in this rule, in addition to any other required records of the pharmacy, shall be available for inspection and copying by the board, its authorized agent, or another authorized agency for a minimum of two years following the date of the record.

40.11(1) *Checking technician training and authorization.* TPV program records shall include all records documenting the successful completion of the pharmacy's training program for each checking technician in the TPV program. The record for each checking technician shall include the following:

a. The name of the technician.

b. The date on which the technician completed the system-specific training for participation in the TPV program.

c. The date on which the technician was authorized to participate in the TPV program.

40.11(2) *Quality assurance program.* TPV program records shall include all records associated with the quality assurance program to evaluate each checking technician in the TPV program, including the dates and results of each quarterly verification; the dates of and reasons for any suspension or revocation of a checking technician's TPV program authorization, identification of corrective action or retraining completed, and the date of the subsequent reinstatement of a checking technician's TPV program authorization; and the dates of and reasons for any disciplinary action taken against a checking technician in connection with the TPV program.

40.11(3) *Quarterly reports.* TPV program records shall include quarterly reports as required pursuant to subrule 40.8(3).

[**ARC 4456C**, IAB 5/22/19, effective 6/26/19]

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

[Filed ARC 9783B (Notice ARC 9557B, IAB 6/15/11), IAB 10/5/11, effective 11/9/11]

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[Editorial change: IAC Supplement 9/8/21]

CHAPTER 41
OUTSOURCING FACILITIES

657—41.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standard of practice for outsourcing facilities that intend to provide compounding services in or into Iowa. The requirements of these rules, in addition to any other board rules applicable to the facility's operation, apply to all Iowa-licensed outsourcing facilities that provide compounded medications in or into Iowa whether pursuant to a patient-specific prescription or not.
[**ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—41.2(155A) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"FDA" means the United States Food and Drug Administration.

"Home state" means the state in which an outsourcing facility is located.

"Outsourcing facility" or *"facility"* means any compounding facility that is registered as an outsourcing facility, as defined in 21 U.S.C. Section 353b, that distributes sterile compounded human drug products without a patient-specific prescription to an authorized agent or practitioner in this state.
[**ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—41.3(155A) Outsourcing facility license. Beginning January 1, 2018, an outsourcing facility shall apply for and obtain an outsourcing facility license from the board prior to providing non-patient-specific compounded human drug products in this state. The applicant shall submit a completed application along with an application fee of $400. An outsourcing facility that intends to distribute controlled substances in or into Iowa shall also, prior to distributing such substances in or into Iowa, apply for and obtain an Iowa controlled substances Act registration pursuant to 657—Chapter 10.

41.3(1) *Application requirements.* The application shall require demographic information about the facility; ownership information; the name, signature and home state license number for the supervising pharmacist; an attestation that the supervising pharmacist has read and understands the laws and rules relating to sterile compounding in Iowa; information about the entity's registered agent; criminal and disciplinary history information; and a description of the scope of services to be provided in Iowa. As part of the application process, the applicant shall also:

a. Submit evidence of possession of a valid registration with the FDA as an outsourcing facility.

b. If one or more inspections have been conducted by the FDA in the five-year period immediately preceding the application, submit a copy of any correspondence from the FDA as a result of the inspection, including but not limited to any form 483s, warning letters, or formal responses, and all correspondence from the applicant to the FDA related to such inspections, including but not limited to formal responses and corrective action plans. In addition, the applicant shall submit evidence of correction of all deficiencies discovered in such inspections and evidence of compliance with all directives from the FDA.

c. Submit evidence that the supervising pharmacist, as described in 21 U.S.C. Section 353b(a), holds a valid pharmacist license in the state in which the facility is located and that such license is in good standing.

d. Submit information to facilitate a national criminal history record check.

41.3(2) *Provision of patient-specific prescriptions.* If an outsourcing facility intends to dispense prescription drugs pursuant to patient-specific prescriptions to individual patients in Iowa, the outsourcing facility shall also obtain and maintain a valid Iowa pharmacy license. If the pharmacy is located in Iowa, the pharmacy shall obtain and maintain a valid Iowa pharmacy license pursuant to 657—Chapter 8; if the pharmacy is located outside Iowa, the pharmacy shall, prior to dispensing prescriptions to patients located in Iowa, obtain and maintain a valid Iowa nonresident pharmacy license pursuant to 657—Chapter 19.

41.3(3) *License renewal.* The outsourcing facility license shall be renewed by January 1 of each year. The facility shall submit the license application and fee as provided in this rule. An outsourcing facility may renew its license beginning November 1 prior to license expiration. An initial outsourcing facility

license issued between November 1 and December 31 shall not require renewal until the following calendar year. The fee for license renewal shall be $400.

a. Delinquent license grace period. If an outsourcing facility license has not been renewed or canceled prior to expiration, but the facility is in the process of renewing the license, the license becomes delinquent on January 1. An outsourcing facility that submits a completed license renewal application, application fee, and late penalty fee of $400 postmarked or delivered to the board office by January 31 shall not be subject to disciplinary action for continuing to provide services to Iowa customers in the month of January.

b. Delinquent license reactivation beyond grace period. If an outsourcing facility license has not been renewed prior to the expiration of the one-month grace period identified in paragraph 41.3(3)*"a,"* the facility may not continue to provide services to Iowa customers. An outsourcing facility that continues to provide services to Iowa customers without a current license may be subject to disciplinary sanctions. An outsourcing facility without a current license may apply for reactivation by submitting an application for license reactivation and a $1,600 reactivation fee. As part of the reactivation application, the facility shall disclose the services, if any, that were provided to Iowa customers while the license was delinquent.

41.3(4) *License changes.* If an outsourcing facility has a change of name, ownership, location or supervising pharmacist, the facility shall submit to the board an outsourcing facility license application and applicable fee within ten days of the FDA's issuance of an updated registration. Following processing of the completed license application and fee, the board shall issue a new license certificate that reflects the change or changes.

41.3(5) *License cancellation.* If an outsourcing facility ceases to be registered as an outsourcing facility with the FDA, the facility shall immediately cease distribution of non-patient-specific compounded drug products in or into this state and shall return its Iowa outsourcing facility license to the board within ten days of such occurrence. Upon receipt, the board shall administratively cancel the outsourcing facility license. If an outsourcing facility intends to discontinue business in this state, the facility shall notify the board in writing of its intent at least 30 days in advance of the discontinuation of services and request that the license be administratively canceled. To the extent possible to avoid unnecessary delays in obtaining product for patients, an outsourcing facility that intends to discontinue services in Iowa should provide advance notice to its customers of the date that the outsourcing facility intends to cease distributing products in this state. The notice requirements of this rule shall not apply in the case of a board-approved emergency or unforeseeable closure, including but not limited to emergency board action, foreclosure, fire, or natural disaster.

[**ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—41.4(155A) Applicability of board rules. An outsourcing facility shall comply with all requirements of this chapter, 657—Chapter 20, and any other board rules relating to the services that are provided to Iowa customers.

41.4(1) *Controlled substances.* An outsourcing facility providing prescription drugs identified as controlled substances under Iowa Code chapter 124 to Iowa customers or patients shall comply with all requirements of 657—Chapter 10.

41.4(2) *Electronic data.* An outsourcing facility utilizing any electronic data processing or transmission devices or services shall comply with all requirements of 657—Chapter 21.

41.4(3) *Patient-specific prescriptions.* An outsourcing facility that also provides patient-specific compounded medications pursuant to a prescription shall comply with all requirements of 657—Chapters 8, 19, and 20.

[**ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—41.5(155A) Reporting discipline and criminal convictions. An outsourcing facility shall provide written notice to the board of any disciplinary or enforcement action imposed by any licensing or regulatory authority on any license or registration held by the facility. Written notice shall be received no later than 30 days after the final action. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. An

outsourcing facility shall provide written notice to the board of any criminal conviction of the facility or of any owner that is related to the operation of the facility no later than 30 days after the conviction. The term "criminal conviction" includes instances when the judgment of conviction or sentence is deferred.
[**ARC 3238C**, IAB 8/2/17, effective 9/6/17]

657—41.6(155A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on an outsourcing facility license for any of the following:

1. Any violation of the Federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the FDA shall be conclusive evidence of a violation.

2. Any conviction of a crime related to prescription drugs or the practice of pharmacy committed by the outsourcing facility, supervising pharmacist, or individual owner, or if the outsourcing facility is an association, joint stock company, partnership, or corporation, by any managing officer.

3. Refusing access to the outsourcing facility or facility records to an agent of the board for the purpose of conducting an inspection or investigation.

4. Failure to maintain licensure pursuant to 657—Chapter 8 or 657—Chapter 19 when dispensing compounded drugs pursuant to patient-specific prescriptions into the state.

5. Any violation of Iowa Code chapter 155A, 124, 124B, 126, or 205 or any rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

[**ARC 3238C**, IAB 8/2/17, effective 9/6/17; **ARC 3857C**, IAB 6/20/18, effective 7/25/18]

These rules are intended to implement Iowa Code sections 124.301 and 155A.13C.

[Filed ARC 3238C (Notice ARC 3038C, IAB 4/26/17), IAB 8/2/17, effective 9/6/17]
[Filed ARC 3857C (Notice ARC 3506C, IAB 12/20/17), IAB 6/20/18, effective 7/25/18]

CHAPTER 42
LIMITED DISTRIBUTOR LICENSES

657—42.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standard of practice for limited drug and device distribution in the state of Iowa. This chapter applies to a person who is involved in the distribution of drugs and devices but who does not meet the definition of a wholesale distributor under federal or state law. In addition to the rules of the board, any distribution of prescription drugs and devices shall be in compliance with all applicable federal and state laws and regulations.
[**ARC 4191C**, IAB 12/19/18, effective 1/23/19]

657—42.2(155A) Definitions. In addition to the definitions found in Iowa Code section 155A.3, which are adopted for the purposes of this chapter, the following definitions shall apply:

"Board" means the Iowa board of pharmacy.

"Distribute" means the delivery or transfer of a prescription drug or device from one person to another.

"Facility manager" means the individual responsible for managing the daily operations of the limited distributor facility.

"Limited distributor" means a person operating or maintaining a location, regardless of the location, where prescription drugs or devices are manufactured, repackaged, distributed at wholesale, or distributed to a patient pursuant to a prescription drug order, who is not eligible for a wholesale distributor license or a pharmacy license. Included in the definition of "limited distributor" are the activities identified in subrule 42.3(1).
[**ARC 4191C**, IAB 12/19/18, effective 1/23/19]

657—42.3(155A) Limited distributor license. Beginning January 1, 2019, no person other than a licensed wholesale distributor, licensed pharmacy, or practitioner shall engage in any of the activities found herein in this state without a limited distributor license. Where operations are conducted at more than one location by a single distributor, each location shall be separately licensed. The applicant shall submit a completed application along with a nonrefundable fee of $175. A limited distributor that engages in distribution of controlled substances into, out of, or within this state shall also obtain a controlled substances Act registration pursuant to 657—Chapter 10.

42.3(1) *License required.* A person engaged in the following activities shall obtain a limited distributor license prior to distribution in or into Iowa:

a. Distribution of a medical gas or device at wholesale or to a patient pursuant to a prescription drug order.

b. Wholesale distribution of a prescription animal drug.

c. Wholesale distribution of a prescription drug, or brokering the distribution of a prescription drug at wholesale, by a manufacturer, a manufacturer's co-licensed partner, or a repackager.

d. Intracompany distribution of a prescription drug, including pharmacy chain distribution centers.

e. Distribution at wholesale of a combination product as defined by the United States Food and Drug Administration, medical convenience kit, intravenous fluid or electrolyte, dialysis solution, radioactive drug, or irrigation or sterile water solution to be dispensed by prescription only.

f. Distribution of a dialysis solution by the manufacturer or the manufacturer's agent to a patient pursuant to a prescription drug order, provided that a licensed pharmacy processes the prescription drug order.

42.3(2) *License optional.* A person engaged in the following activities may, but is not required to, obtain a limited distributor license for distribution in or into Iowa:

a. Distribution of nonprescription drugs or devices with or without a patient-specific prescription.

b. Distribution of medical devices exclusively to a health care practitioner for use in the normal course of professional practice ("professional use").

c. Distribution of blood and blood products that are not subject to the federal Drug Supply Chain Security Act (DSCSA).

42.3(3) *Application.* The applicant shall complete an application which requires demographic information about the limited distributor, ownership information, information about the limited distributor's registered agent located in Iowa, information about the limited distributor's licensure with other state and federal regulatory authorities, criminal and disciplinary history information, information regarding the facility manager, and a detailed description of the services to be provided in this state. An application for a limited distributor 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, including opening for business, within six months of receipt by the board of the required application(s). The following shall also be submitted by the applicant for the application to be considered complete:

a. Evidence of the mandatory physical inspection of the distribution facility pursuant to subrule 42.3(7).

b. Attestation by facility manager. The applicant shall submit attestation that the facility manager has adequate experience in prescription drug and device distribution; is actively involved in the daily operation of the distribution facility; maintains a functional understanding of federal and state laws, rules, and regulations pertaining to drug and device distribution, as applicable; and has no felony convictions or convictions related to prescription drug and device distribution, including distribution of controlled substances.

42.3(4) *License renewal.* A limited distributor license shall be renewed before January 1 of each year and may be renewed as early as November 1 prior to expiration. The limited distributor shall submit a completed application and nonrefundable application fee as required in this rule.

a. Delinquent license grace period. If a limited distributor license has not been renewed or canceled prior to expiration, the license becomes delinquent on January 1. A limited distributor that submits a completed license renewal application, nonrefundable application fee, and nonrefundable late penalty fee of $175 postmarked or delivered to the board by January 31 shall not be subject to disciplinary action for continuing to provide services in this state in the month of January.

b. Delinquent license reactivation beyond grace period. If a limited distributor license has not been renewed prior to the expiration date of the one-month grace period identified in paragraph 42.3(4)*"a,"* the limited distributor may not operate or do business in Iowa, unless the activities conducted are those identified in subrule 42.3(2). A limited distributor that continues to do business in Iowa without a current license as required in subrule 42.3(1) may be subject to disciplinary sanctions pursuant to the provisions of 657—subrule 36.6(2). A limited distributor without a current license may apply for reactivation by submitting a license application for reactivation and a nonrefundable reactivation fee of $500. As part of the reactivation application, the limited distributor shall disclose the services, if any, that were provided in this state while the license was delinquent.

42.3(5) *License changes.* If a distributor has a change of name, ownership, or location, a limited distributor license application with a nonrefundable application fee as provided in subrule 42.3(3) shall be submitted to the board. A change of ownership occurs when the owner listed on the limited distributor's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the limited distributor's most recent application. A change of limited distributor location within Iowa, if the new location was not a licensed limited distributor immediately prior to the relocation, shall require a self-inspection as provided in subrule 42.3(7). A limited distributor that has submitted a license change application may continue to service Iowa customers while its license change is pending final approval.

a. For a distributor located in Iowa, a completed application shall be submitted to the board as far in advance as possible prior to the change of name, ownership, or location.

b. For a distributor located outside of Iowa:

(1) If the home state licenses or registers the facility, a completed application shall be submitted within ten days of receipt of an updated license or registration from the home state.

(2) If the home state does not license or register the facility, a completed application shall be submitted as far in advance as possible prior to the change of name, ownership, or location.

c. When a distributor changes its name or location, the distributor shall provide advance written notice of the change to each Iowa customer and patient.

d. Applications for license changes shall be timely submitted pursuant to this subrule. A licensed limited distributor that has timely submitted a license change application and fee may continue to service Iowa customers while the license change is pending final approval. An applicant that has submitted an application for license changes after the required date of submission pursuant to this subrule but within 30 days of the required date of submission shall be assessed a nonrefundable late penalty fee of $175 in addition to the license fee. An applicant that has submitted an application for license changes 31 days or later following the required date of submission pursuant to this subrule shall be assessed a nonrefundable reactivation fee of $500.

42.3(6) *License cancellation.* If a limited distributor intends to discontinue service into, out of, or within this state, it shall:

a. Notify the board as far in advance as possible of the limited distributor's intent to discontinue services and shall request that the license be administratively canceled. The notification shall include the name, address, and Iowa license number of the pharmacy or distributor at which prescription, patient, and distribution records will be maintained.

b. Ensure that prescription and patient records are transferred to another Iowa-licensed distributor or pharmacy.

c. To the extent possible to avoid unnecessary delays in the availability of services to Iowa customers and patients, provide advance written notice to customers and patients of the date that the distributor intends to cease provision of services.

42.3(7) *Inspection of limited distributor facility.* Each limited distributor location seeking initial or renewal licensure shall, prior to issuance of a license certificate, complete and submit for evaluation a self-inspection packet provided by the board.

42.3(8) *Change in facility manager.* If a distributor has a change in facility manager, the licensee shall provide notice to the board on forms provided by the board within ten days of the change.

[**ARC 4191C**, IAB 12/19/18, effective 1/23/19; **ARC 5008C**, IAB 3/25/20, effective 4/29/20]

657—42.4 and **42.5** Reserved.

657—42.6(155A) Grounds for denial. The board may deny a limited distributor license application, or refuse to renew a license, for any of the following:

1. Any criminal convictions of the applicant related to the distribution of drugs or devices;
2. Any felony convictions of the applicant;
3. Insufficient experience in the distribution of prescription drugs or devices, including a lack of knowledge regarding the requirements of applicable federal and state laws or regulations;
4. The furnishing of false or fraudulent material;
5. Suspension, revocation, or other disciplinary action taken by the licensing authority of another state or federal agency against any license or registration currently or previously held by the applicant;
6. Noncompliance with licensing requirements under previously granted licenses, if any;
7. Noncompliance with the requirements to maintain or make available to the board, its agents, or to federal, state, or local law enforcement officials those records required to be maintained;
8. Conducting transactions with a person that is not properly licensed, registered, or authorized; and
9. Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

[**ARC 4191C**, IAB 12/19/18, effective 1/23/19]

657—42.7(155A) Policies and procedures.

42.7(1) Distributors shall have for all aspects of the distributor's operation policies and procedures that, at a minimum, address the rules in this chapter and any other applicable federal, state, and local laws, rules, and regulations.

42.7(2) The policies shall address, at a minimum:

a. Security of the facility and of patient information;

b. Storage of products, including proper storage conditions and handling of outdated, recalled, and returned products;

c. Records, including the retention period for all required records;

d. Security, storage and records for products in the possession of a distributor's authorized representative; and

e. Employment of personnel with education and experience appropriate to the responsibilities of the position held.

[**ARC 4191C**, IAB 12/19/18, effective 1/23/19]

657—42.8 and **42.9** Reserved.

657—42.10(155A) Requirements.

42.10(1) *Physical requirements.* A distributor's location shall:

a. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

b. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

c. Have a quarantine area for storage of outdated, damaged, unsafe, deteriorated, misbranded, or adulterated products and for any suspect products;

d. Be maintained in a clean and orderly condition;

e. Be free from infestation by insects, rodents, birds, or vermin of any kind.

42.10(2) *Operation requirements.* Distributors shall operate in compliance with all applicable federal, state, and local laws, rules, and regulations.

a. *Purchasing.* Distributors shall purchase products from a legitimate source that is properly licensed in the state in which it is located and that is properly licensed in the distributor's home state, if such licensure is required. Distributors shall exercise due diligence in determining the legitimacy of a product's source and maintain documentation of the distributor's verification of the legitimate source.

b. *Examination of materials.* Distributors shall ensure, upon receipt and prior to distribution, that a product is suitable for distribution.

c. *Verification.* Qualified personnel shall verify, prior to distribution, that the product matches the order for which the product is being distributed.

d. *Instructions for use.* Qualified personnel shall provide to the patient or the patient's caregiver adequate instructions for use when a product is distributed pursuant to a prescription order.

[**ARC 4191C**, IAB 12/19/18, effective 1/23/19]

657—42.11 Reserved.

657—42.12(155A) Records. Distributors shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of products, including outdated, damaged, deteriorated, misbranded, or adulterated products.

42.12(1) *Transaction records.* Records for receipt and distribution transactions for all products shall include the following information:

a. The source of the products, including the name and principal address of the seller or transferor and the address of the location from which the products were shipped;

b. The identity and quantity of the products received or distributed;

c. The date of receipt or distribution of the products; and

d. The identity of the purchaser of the products, including the name and principal address of the purchaser or transferee and the address to which the products were shipped or distributed.

42.12(2) *Prescription order records.* Each prescription order that results in the distribution of a product shall be retained, in the original format received, and be available for inspection and copying by the board, its representative, or other authorized individual for at least two years from the date of last activity of the prescription order.

a. Prescription orders shall contain all the required elements identified in Iowa Code section 155A.27.

b. Prescription orders for noncontrolled prescription drugs shall be valid for no longer than 18 months following the date issued or 13 fills, whichever is less.

c. A one-month supply of a medical gas, such as oxygen, shall be considered to be a single refill. Such prescription must be reissued at least every 13 months.

d. Prescription orders for controlled substances shall be valid for no longer than six months following the date issued or six fills, whichever is less.

42.12(3) *Records maintained.* All records generated pursuant to the distributor's policies and procedures, this chapter, and all federal, state, and local rules, laws and regulations shall be maintained, readily retrievable, and available for inspection and copying by the board, its representative, or other authorized individual for at least two years from the date of the record.

42.12(4) *Confidentiality of patient information.* Any patient information in the possession of a distributor shall be maintained in compliance with the patient confidentiality and security requirements of 657—Chapter 8, 657—Chapter 21, and federal law.

[**ARC 4191C**, IAB 12/19/18, effective 1/23/19]

657—42.13 Reserved.

657—42.14(155A) Reporting discipline and criminal convictions. No later than 30 days after the final action, a limited distributor shall provide to the board written notice, including an unredacted copy of the action or order, of any disciplinary or enforcement action imposed by any licensing or regulatory authority on any license or registration held by the distributor. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary period, suspension, revocation, and voluntary surrender. No later than 30 days after the conviction, a limited distributor shall provide to the board written notice, including an unredacted copy of the judgment of conviction or sentence, of any criminal conviction of the distributor, any owner of the distributor, or any individual responsible for managing the daily operations of the distribution facility, if the conviction is related to prescription drug or device distribution. The term "criminal conviction" includes instances when the judgment of conviction or the sentence is deferred.

[**ARC 4191C**, IAB 12/19/18, effective 1/23/19]

657—42.15(155A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a limited distributor license for any of the following:

1. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulation promulgated under the Act. A warning letter issued by the United States Food and Drug Administration shall be conclusive evidence of a violation.
2. Any conviction of a crime related to the distribution of prescription drugs or devices committed by the distributor, its owners, or the facility manager.
3. Refusing access to the distribution facility or records to an agent of the board for the purpose of conducting an inspection or investigation.
4. Failure to maintain registration pursuant to 657—Chapter 10 when distributing controlled substances into, out of, or within this state.
5. Any act of unethical or unprofessional conduct by an employee of the distributor.
6. Any violation of Iowa Code chapter 124, 126, 155A, or 205, or rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

[**ARC 4191C**, IAB 12/19/18, effective 1/23/19]

These rules are intended to implement Iowa Code sections 124.301 through 124.308, 126.3, 126.9 through 126.12, 126.22, 155A.3, 155A.4, 155A.13, 155A.17, 155A.21, 155A.23, and 155A.42.

[Filed ARC 4191C (Notice ARC 3975C, IAB 8/29/18), IAB 12/19/18, effective 1/23/19]

[Filed ARC 5008C (Notice ARC 4691C, IAB 10/9/19), IAB 3/25/20, effective 4/29/20]

CHAPTER 43
THIRD-PARTY LOGISTICS PROVIDER LICENSES

657—43.1(155A) Purpose and scope. The purpose of this chapter is to establish the minimum standards required of third-party logistics providers as defined in Iowa Code section 155A.3 in this state pursuant to national standards as established by federal law. This chapter applies to logistics providers operating in or into this state. A 3PL does not include an entity that solely engages in shipping activities. Applicable activities of a 3PL include, but are not limited to, picking, packing, and shipping; inventory management; and warehousing or distribution management. In the event the requirements of this chapter directly conflict with any federal law or regulation, the federal law or regulation shall supersede the requirements in this chapter.
[**ARC 4192C**, IAB 12/19/18, effective 1/23/19]

657—43.2(155A) Definitions. For the purposes of this chapter, the definitions found in Iowa Code section 155A.3 and the following definitions apply.

"Board" means the Iowa board of pharmacy.

"Facility manager" means the individual who is responsible for the daily operation of a third-party logistics licensed location.

"FDA" means the United States Food and Drug Administration.

"Home state" means the state in which a third-party logistics provider is located.

"Third-party logistics provider" or *"3PL"* means an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product nor have responsibility to direct the sale or other disposition of the product.
[**ARC 4192C**, IAB 12/19/18, effective 1/23/19]

657—43.3(155A) 3PL license. Beginning April 1, 2019, every 3PL as defined in rule 657—43.2(155A), wherever located, that provides or coordinates warehousing or other logistics services of products 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 such logistics operations. Where activities are conducted at more than one location by a single 3PL, each location shall be separately licensed. The applicant shall submit a completed application with a nonrefundable application fee of $750. A 3PL that handles controlled substances shall also obtain a controlled substances Act registration pursuant to 657—Chapter 10.

43.3(1) *Application.* The applicant shall complete an application which requires demographic information about the 3PL, ownership information, information about the 3PL's registered agent located in Iowa, information about the 3PL's licensure or registration with other state and federal regulatory authorities, criminal and disciplinary history information, and a description of the scope of services to be provided in Iowa. If the applicant is not located in Iowa, the applicant shall submit evidence that the applicant has a valid license or registration in the home state or provide evidence that the home state does not require licensure. The applicant shall provide evidence of current drug distributor accreditation by the National Association of Boards of Pharmacy (NABP), the National Coalition for Drug Quality and Security (NCDQS), or another accreditation body approved by the board. This requirement does not apply to new applicants located in Iowa which must undergo an opening inspection by a board compliance officer or agent of the board prior to issuance of an initial license pursuant to subrule 43.3(3). 3PL distributors located in Iowa shall provide evidence of drug distributor accreditation on or before license renewal. An application for a 3PL 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, including opening for business, within six months of receipt by the board of the required application(s).

43.3(2) *Facility manager.* The applicant shall attest that the facility manager has adequate experience in providing or coordinating warehousing or other logistics services of products; is actively involved in the daily operation of the facility; maintains a functional understanding of federal and state laws, rules, and regulations pertaining to drug and device distribution; and has no felony conviction or convictions

related to prescription drug or device distribution, including distribution of controlled substances. Upon receipt of a licensure application, the board shall provide a fingerprint packet to the applicant's facility manager, who shall submit the completed fingerprint packet and a signed waiver form to facilitate a national criminal history background check of the facility manager. The cost of the evaluation of the fingerprint packet and the Iowa division of criminal investigation and the United States Federal Bureau of Investigation criminal history background checks will be assessed to the applicant.

43.3(3) *Inspection of new 3PL facility.* Each new 3PL location seeking licensure shall be inspected prior to issuance of a license.

a. Iowa location. If the applicant is located within Iowa, an inspection shall be conducted by the board or its authorized agent prior to issuance of the license and periodically thereafter.

b. Nonresident location. If the applicant is located outside of Iowa, an inspection shall be conducted by the applicant's home state regulatory authority or another board-approved inspecting authority and a report of such inspection shall be submitted with the application. The application shall also include evidence of corrective action taken to satisfy any deficiencies identified in the inspection report and compliance with all legal directives of the inspecting authority, if applicable. With each license renewal and license reactivation for a 3PL outside of Iowa, the application shall include a copy of the most recent inspection report issued as a result of an inspection conducted by the home state regulatory authority or other board-approved inspecting authority.

43.3(4) *License renewal.* The 3PL license shall be renewed by April 1 each year. The 3PL shall submit the completed license application and nonrefundable application fee of $750. A 3PL may renew its license beginning February 1 prior to license renewal. An initial 3PL license issued between February 1 and March 31 shall not require renewal until the following calendar year.

a. Delinquent license grace period. If a 3PL license has not been renewed or canceled prior to expiration, but the 3PL is in the process of renewing the license, the license becomes delinquent on April 1. A 3PL that submits a completed license renewal application, nonrefundable application fee, and nonrefundable late penalty fee of $750 postmarked or delivered to the board by April 30 shall not be subject to disciplinary action for continuing to provide services to Iowa customers in the month of April.

b. Delinquent license reactivation beyond grace period. If a 3PL license has not been renewed prior to the expiration of the one-month grace period identified in paragraph 43.3(4)*"a,"* the 3PL may not continue to provide services to Iowa customers. A 3PL that continues to provide services to Iowa customers without a current license may be subject to disciplinary sanctions. A 3PL without a current license may apply for reactivation by submitting a license application for reactivation and a nonrefundable reactivation fee of $2,000. As part of the reactivation application, the 3PL shall disclose the services, if any, that were provided to Iowa customers while the license was delinquent.

43.3(5) *License changes.* When a licensed 3PL changes its name, ownership, location, or facility manager, a completed 3PL license application with nonrefundable fee of $750 shall be submitted to the board. A change of ownership occurs when the owner listed on the 3PL's most recent application changes or when there is a change affecting the majority ownership interest of the owner listed on the 3PL's most recent application. A change of 3PL location within Iowa, if the new location was not a licensed 3PL immediately prior to the relocation, shall require an on-site inspection of the new location as provided in subrule 43.3(3). A 3PL that has submitted a license change application may continue to service Iowa customers while its license change is pending final approval.

a. Locations in Iowa. An application for license change shall be submitted to the board as far in advance as possible prior to the anticipated change.

b. Locations outside of Iowa. An application for license change shall be submitted to the board within ten days of the 3PL's receipt of an updated license or registration from the home state regulatory authority or the FDA, as applicable.

c. License change application submission. Applications for license changes shall be timely submitted pursuant to this subrule. A licensed 3PL that has timely submitted a license change application and fee may continue to service Iowa customers while the license change is pending final approval. An applicant that has submitted an application for license changes after the required date of submission pursuant to this subrule but within 30 days of the required date of submission shall be

assessed a nonrefundable late penalty fee of $750 in addition to the license fee. An applicant that has submitted an application for license changes 31 days or later following the required date of submission pursuant to this subrule shall be assessed a nonrefundable reactivation fee of $2,000.

d. Change in facility manager. When a 3PL has a change in facility manager, a new facility manager shall be identified pursuant to this paragraph. If a permanent facility manager is not currently the facility manager of a licensed facility, the facility manager shall submit to a criminal background check.

(1) If a permanent facility manager has been identified at the time of the vacancy, a 3PL license application identifying the new permanent facility manager, along with the appropriate fee, shall be submitted to the board within ten days of the vacancy.

(2) If no permanent facility manager has been identified at the time of the vacancy, a temporary facility manager shall be identified and notice of such shall be submitted in writing to the board within ten days of the vacancy. A temporary facility manager shall not be required to submit a fingerprint packet and signed waiver to facilitate a national criminal history check unless the temporary facility manager subsequently is identified as the permanent facility manager. Within 90 days of the vacancy, a permanent facility manager shall be identified and a 3PL license application identifying the permanent facility manager, along with the appropriate fee, shall be submitted to the board.

43.3(6) *License cancellation.* If a 3PL intends to discontinue service into, out of, or within this state, the licensee shall notify the board and shall request that the license be administratively canceled.

[**ARC 4192C**, IAB 12/19/18, effective 1/23/19; **ARC 5008C**, IAB 3/25/20, effective 4/29/20; **ARC 5351C**, IAB 12/30/20, effective 2/3/21]

657—43.4 Reserved.

657—43.5(155A) Compliance with federal and state laws. A 3PL is responsible for complying with all applicable federal and state laws, including those not specifically identified in this chapter.

1. A licensed 3PL shall meet the requirements set forth in the Drug Supply Chain Security Act, 21 U.S.C. §360eee-3, relating to third-party logistics and regulations promulgated thereunder.

2. A licensed 3PL shall permit agents of the board to enter and inspect the facility for compliance with federal and state laws. A licensed 3PL shall cooperate with other regulatory or law enforcement officials with jurisdiction over the facility.

[**ARC 4192C**, IAB 12/19/18, effective 1/23/19]

657—43.6(155A) Policies and procedures. A licensed 3PL shall establish, maintain, and adhere to written policies and procedures that are in compliance with standards established pursuant to federal and Iowa law and which address, at a minimum, the following:

1. Storage practices;
2. Maintaining adequate security;
3. Receipt, inventory, shipment, and distribution of product;
4. Theft or loss;
5. Inventory errors and inaccuracies;
6. Manufacturer recalls and withdrawals;
7. Emergency and disaster plan;
8. Records, including the retention period for all required records;
9. Drug diversion detection and prevention; and
10. Outdated, adulterated, or suspect products.

[**ARC 4192C**, IAB 12/19/18, effective 1/23/19]

657—43.7 and **43.8** Reserved.

657—43.9(155A) Reporting discipline and criminal conviction. No later than 30 days after the final action, a 3PL shall provide to the board written notice, including an unredacted copy of the action or order, of any disciplinary sanction imposed on any license or registration held by the 3PL or its owner or owners. Discipline may include, but is not limited to, fine or civil penalty, citation or reprimand, probationary

period, suspension, revocation, and voluntary surrender. No later than 30 days after the conviction, a 3PL shall provide to the board written notice, including an unredacted copy of the judgment of conviction or sentence, of any criminal convictions related to product distribution, including convictions of any of its owners, or its facility manager. The term "criminal conviction" includes instances when the judgment of conviction or the sentence is deferred.
[**ARC 4192C**, IAB 12/19/18, effective 1/23/19]

657—43.10(155A) Discipline. Pursuant to 657—Chapter 36, the board may fine, suspend, revoke, or impose other disciplinary sanctions on a 3PL license for any of the following:

1. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulation promulgated under the Act related to third-party logistics and drug or device distribution.
2. Any conviction of a crime related to the distribution of prescription drugs or devices committed by the 3PL, its owners, or the facility manager.
3. Refusing access to the 3PL facility or records to an agent of the board or other authorized regulatory authority for the purpose of conducting an inspection or investigation.
4. Failure to maintain registration pursuant to 657—Chapter 10 when distributing controlled substances into, out of, or within this state.
5. Any act of unethical or unprofessional conduct by an employee of the 3PL.
6. Any violation of Iowa Code chapter 124, 126, 155A, or 205, or rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

[**ARC 4192C**, IAB 12/19/18, effective 1/23/19]

These rules are intended to implement Iowa Code chapter 124B and sections 124.301 through 124.308, 126.3, 126.9 through 126.12, 155A.3, 155A.4, 155A.17A, and 155A.40 and the federal Drug Supply Chain Security Act.

[Filed ARC 4192C (Notice ARC 3976C, IAB 8/29/18), IAB 12/19/18, effective 1/23/19]
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[Filed ARC 5351C (Notice ARC 5171C, IAB 9/9/20), IAB 12/30/20, effective 2/3/21]

CHAPTERS 44 to 99
Reserved

CHAPTER 100
IOWA REAL-TIME ELECTRONIC PSEUDOEPHEDRINE TRACKING SYSTEM

657—100.1(124) Purpose and scope. Iowa Code section 124.212B directs the governor's office of drug control policy to establish a real-time electronic repository to monitor and control the sale of Schedule V products that are not listed in another controlled substance schedule and that contain any detectible amount of pseudoephedrine, its salts, or optical isomers, or salts of optical isomers; ephedrine; or phenylpropanolamine. All pharmacies dispensing such products without a prescription shall electronically report all such sales to the repository. The real-time electronic repository shall be under the control of and administered by the governor's office of drug control policy. Both the governor's office of drug control policy and the board of pharmacy are directed to adopt rules relating to the real-time electronic repository and have jointly adopted these rules. These rules establish the pseudoephedrine tracking system (PTS).
[**ARC 8893B**, IAB 6/30/10, effective 9/1/10; **ARC 3100C**, IAB 6/7/17, effective 7/12/17]

657—100.2(124) Definitions. As used in this chapter:

"Attempted purchase" means a proposed transaction for the dispensing of a product that is entered by a dispenser into the electronic pseudoephedrine tracking system, which transaction is not completed because the system recommends that the transaction be denied pursuant to the quantity limits established in Iowa Code section 124.213.

"Board" means the board of pharmacy.

"Dispenser" means a licensed Iowa pharmacist, a registered pharmacist-intern under the direct supervision of a pharmacist preceptor, a registered pharmacy technician under the direct supervision of a pharmacist, except as authorized in 657—Chapter 13, or a registered pharmacy support person under the direct supervision of a pharmacist.

"Law enforcement officer" means all of the following:

1. State police officer.
2. City or county police officer.
3. Sheriff or deputy sheriff.
4. State or public university safety and security officer.
5. Department of natural resources officer.
6. Certified or full-time peace officer of this or another state.
7. Federal peace officer.
8. Criminal analyst assigned to a law enforcement agency.
9. Probation or parole officer.

"Office" means the governor's office of drug control policy.

"Product" means a Schedule V drug product that is not listed in another controlled substance schedule and that contains any detectible amount of pseudoephedrine, its salts, or optical isomers, or salts of optical isomers; ephedrine; or phenylpropanolamine.

"Pseudoephedrine tracking system" or *"PTS"* means the real-time electronic repository established to monitor and control the sale of products and administered by the governor's office of drug control policy.

"Purchaser" means an individual 18 years of age or older who purchases or attempts to purchase a product.
[**ARC 8893B**, IAB 6/30/10, effective 9/1/10; **ARC 0153C**, IAB 6/13/12, effective 7/18/12; **ARC 3100C**, IAB 6/7/17, effective 7/12/17; **ARC 4701C**, IAB 10/9/19, effective 11/13/19]

657—100.3(124) Electronic pseudoephedrine tracking system (PTS). Unless granted an exemption by the office pursuant to these rules, all pharmacies dispensing products as defined in rule 657—100.2(124) without a prescription are required to participate in the PTS pursuant to Iowa Code section 124.212B.

100.3(1) *Reporting elements.* The record of a completed purchase or attempted purchase of a product without a prescription shall contain the following:

a. The name and address of the purchaser.

b. A current government-issued photo identification number.

c. The electronic signature of the purchaser. If a pharmacy is not able to secure or record an electronic signature, a hard-copy signature logbook shall be utilized and maintained by the pharmacy. Each record in the logbook shall include the purchaser's signature and shall identify the purchase by transaction number.

d. Date and time of purchase.

e. The name and quantity of the product purchased, including the total milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine contained in the product.

f. The name or unique identification of the dispenser who approved the dispensing of the product.

100.3(2) *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.

100.3(3) *Denial of transactions and overrides.*

a. If an individual attempts to purchase a product in violation of these rules, the PTS shall:

(1) Notify the dispenser at the time of sale; and

(2) Recommend that the dispenser deny the transaction.

b. The PTS shall provide an override feature for use by a dispenser to allow completion of the sale. A dispenser utilizing the override feature shall document the reason that, in the professional judgment of the dispenser, it is necessary to override the recommendation of the PTS to deny the transaction.

100.3(4) *Availability of electronic PTS.* If the electronic PTS is unavailable for use, the dispenser shall maintain a written record of each transaction pursuant to 657—subrule 10.34(6). The dispenser shall enter the information from the written record into the PTS within 72 hours of the time the PTS is again available and shall include in the electronic record that the record is a delayed entry.

[**ARC 8893B**, IAB 6/30/10, effective 9/1/10; **ARC 0153C**, IAB 6/13/12, effective 7/18/12; **ARC 3100C**, IAB 6/7/17, effective 7/12/17; **ARC 3345C**, IAB 9/27/17, effective 11/1/17; **ARC 4701C**, IAB 10/9/19, effective 11/13/19]

657—100.4(124) Access to database information and confidentiality. Information collected in the PTS is confidential unless otherwise ordered by a court or released by the office pursuant to state or federal law. Information may not be released except as provided by this rule.

100.4(1) *PTS administrators.* PTS administrators shall be provided access to the PTS for the purpose of searching and retrieving reports only by articulating reasonable suspicion or providing a case number or reference number for an ongoing investigation. PTS administrators shall also be provided information on purchasers directly from the PTS. This information may be sent directly to law enforcement officers pursuant to paragraph 100.4(2)*"e"* for purposes of investigation.

100.4(2) *Law enforcement release.* PTS reports may be provided to a law enforcement officer pursuant to rule 657—100.4(124).

a. A law enforcement officer shall register with the PTS prior to requesting reports. To ensure the identity of the officer and to maintain confidentiality of PTS information, the officer's identity shall be verified and registration shall be approved by the office or the administrator for the officer's agency.

b. Law enforcement officers shall be given direct access to all data from the PTS pursuant to the federal Combat Methamphetamine Epidemic Act and 21 CFR § 1314.45.

c. If a law enforcement officer requests PTS information directly from the PTS, the law enforcement officer shall enter the purpose of the request into the PTS and shall certify the request is part of the officer's official duties.

100.4(3) *Statistical data.* The PTS administrator, following establishment of confidentiality, may provide summary, statistical, or aggregate data to public or private entities for statistical, research, or educational purposes. Prior to release of any such data, the administrator shall remove any information

that could be used to identify an individual patient, dispenser, or other person who is the subject of or identified in the PTS information or data.

100.4(4) *Patients.* A patient may request and receive information regarding products reported to have been purchased by the patient.

a. A patient may submit a signed, written request for records of the patient's purchases and attempted purchases 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 PTS administrator or authorized staff member of the office located at Oran Pape State Office Building, 215 East 7th Street, Fifth Floor, Des Moines, Iowa 50319. The patient shall 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 PTS.

b. A patient who is unable to personally deliver the request to the office 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 current government-issued photo identification, and that certified copy shall be submitted with the written request. The request shall be submitted to the governor's office of drug control policy at the address identified in paragraph 100.4(4)*"a."*

100.4(5) *Regulatory officers.* Regulatory agencies that supervise or regulate a health care practitioner shall be able to access information from the PTS 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 director of a regulatory agency with jurisdiction over a practitioner, or the director's designee, who seeks access to PTS information for an investigation shall submit to the PTS administrator in a format established by the office 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.

100.4(6) *Pharmacy administrators.* A pharmacy, an authorized employee of a pharmacy, or a licensed pharmacist shall be provided access to the stored PTS information only for the limited purpose of determining the sales made by the pharmacy. A pharmacy shall be able to print the pharmacy's sales records for any product during any specified period of time upon the request of the board or an agent of the board.

100.4(7) *Court orders and subpoenas.* The PTS administrator shall provide database information in response to a court order or a county attorney subpoena or other subpoena issued by a court upon a determination of probable cause.

[**ARC 8893B**, IAB 6/30/10, effective 9/1/10; **ARC 9161B**, IAB 10/20/10, effective 9/30/10; **ARC 0153C**, IAB 6/13/12, effective 7/18/12; **ARC 3100C**, IAB 6/7/17, effective 7/12/17]

657—100.5(124) Violations. Violations of provisions of these rules or Iowa Code section 124.212A, 124.212B, or 124.213 may subject the violator to criminal prosecution.

[**ARC 8893B**, IAB 6/30/10, effective 9/1/10; **ARC 3100C**, IAB 6/7/17, effective 7/12/17]

These rules are intended to implement Iowa Code sections 124.212, 124.212A, 124.212B, and 124.213.

[Filed ARC 8893B (Notice ARC 8666B, IAB 4/7/10), IAB 6/30/10, effective 9/1/10]
[Filed Emergency ARC 9161B, IAB 10/20/10, effective 9/30/10]
[Filed ARC 0153C (Notice ARC 0053C, IAB 3/21/12), IAB 6/13/12, effective 7/18/12]
[Filed ARC 3100C (Notice ARC 2858C, IAB 12/7/16), IAB 6/7/17, effective 7/12/17]
[Filed ARC 3345C (Notice ARC 3136C, IAB 6/21/17), IAB 9/27/17, effective 11/1/17]
[Filed ARC 4701C (Notice ARC 4570C, IAB 7/31/19), IAB 10/9/19, effective 11/13/19]