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.

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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.

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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.

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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).

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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).
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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.

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