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.
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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.
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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.

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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.

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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.
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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, 124A, 124B, 126, or 205 or any rule of the board, including the disciplinary grounds set forth in 657—Chapter 36.

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These rules are intended to implement Iowa Code sections 124.301 and 155A.13C.

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