

657—41.3(155A) Outsourcing facility license. 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.
- e. Submit evidence of a satisfactory inspection conducted by the home state regulatory authority or an entity approved by the board in accordance with subrule 41.3(6) along with 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.

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.

a. License change application submission. 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. A change of ownership occurs when the owner listed on the outsourcing facility's most recent application changes.

b. Delinquent license change application submission. An outsourcing facility that 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 \$400 in addition to the license fee. An outsourcing facility that 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 \$1,600.

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.

41.3(6) Inspection requirements. An outsourcing facility submitting any application for licensure, except when related to a change in location or except when the outsourcing facility is located in Iowa and will be subject to an opening inspection prior to issuance of an initial license, 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 outsourcing facility was in operation. Except when the facility is located in Iowa and seeking initial licensure, an inspection prior to the initial opening of the facility shall not satisfy this requirement.

c. The inspection report demonstrates compliance with good manufacturing practices and addresses all aspects of the outsourcing facility's business that will be conducted in Iowa.

d. The inspection was performed by or on behalf of the home state licensing authority, if available.

41.3(7) Qualified inspector. If the home state licensing authority has not conducted an inspection satisfying the inspections requirements identified in subrule 41.3(6), the outsourcing facility shall submit an inspection report issued by one of the following:

a. Another qualified entity if the entity is preapproved by the board.

b. An authorized agent of the board. The board may recover from an outsourcing facility, prior to the issuance of an outsourcing facility license, the costs associated with conducting an inspection.

41.3(8) License verification fee. The board may require a nonrefundable fee of \$15 for completion of a request for written license verification of any outsourcing facility license.

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