

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to outsourcing facilities

The Board of Pharmacy hereby amends Chapter 41, “Outsourcing Facilities,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 147.76, 147.80, and 155A.13C.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 147.80 and 155A.13C.

Purpose and Summary

This rule making, a result of an overall five-year review as required in Iowa Code section 17A.7(2), provides:

- More detailed information for applicants relating to the inspection requirement provided in Iowa Code section 155A.13C(1)“e”;
- Clarification on when a change of ownership is determined to have occurred, necessitating a license change;
- Late penalty fees to be assessed when an outsourcing facility is not timely in submitting an application for license changes; and
- A fee to be assessed to a licensee for written verification of a license when the Board’s online verification system is available at no charge.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on July 27, 2022, as **ARC 6422C**. No public comments were received. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Board on October 25, 2022.

Fiscal Impact

The fiscal impact of this rule making to the State of Iowa is unknown. The intention of this rule making is to incentivize licensees to timely submit license change applications and to utilize the Board’s online verification system at no charge when license verification is needed.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on January 4, 2023.

The following rule-making action is adopted:

Amend rule 657—41.3(155A) as follows:

657—41.3(155A) Outsourcing facility license. ~~Beginning January 1, 2018, an~~ 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. to d. No change.

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) and 41.3(3) No change.

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) No change.

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.

[Filed 11/2/22, effective 1/4/23]

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 11/30/22.