155A.13C Outsourcing facility license — renewal, cancellation, denial, discipline.

1. *License required.* Any compounding facility that is registered as an outsourcing facility, as defined in 21 U.S.C. §353b, that distributes sterile compounded human drug products without a patient-specific prescription to an authorized agent or practitioner in this state shall obtain an outsourcing facility license from the board prior to engaging in such distribution. If an outsourcing facility dispenses prescription drugs pursuant to patient-specific prescriptions to patients in Iowa, the outsourcing facility shall obtain and maintain a valid Iowa pharmacy license or Iowa nonresident pharmacy license under this chapter. The board shall make available an application form for an outsourcing facility license and shall require such information it deems necessary to fulfill the purposes of this section. An outsourcing facility shall do all of the following in order to obtain an outsourcing facility license from the board:

a. Submit a completed application form and application fee as determined by the board.

b. Submit evidence of possession of a valid registration as an outsourcing facility with the United States food and drug administration.

c. If one or more inspections have been conducted by the United States food and drug administration in the five-year period immediately preceding the application, submit a copy of any correspondence from the United States food and drug administration 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 United States food and drug administration 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 United States food and drug administration.

d. Submit evidence that the supervising pharmacist, as described in 21 U.S.C. §353b(a), holds a valid pharmacist license in the state in which the facility is located and that such license is in good standing.

e. Submit evidence of a satisfactory inspection conducted by the home state regulatory authority or an entity approved by the board in the two-year period immediately preceding the application which demonstrates compliance with current good manufacturing practices. 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 home state regulatory authority or entity approved by the board. The board may recover from an outsourcing facility, prior to the issuance of a license or license renewal, the costs associated with conducting an inspection by or on behalf of the board for purposes of satisfying the requirements of this paragraph.

2. *License renewal.* An outsourcing facility shall renew its license on or before January 1 annually. In order to renew an outsourcing facility license, an outsourcing facility shall submit a completed application and fee as determined by the board, and shall fulfill all of the requirements of subsection 1. An outsourcing facility shall pay an additional fee for late renewal as determined by the board.

3. *License cancellation.* If a facility ceases to be registered as an outsourcing facility with the United States food and drug administration, the facility shall notify the board in writing and shall surrender its Iowa outsourcing facility license to the board within thirty days of such occurrence. Upon receipt, the board shall administratively cancel the outsourcing facility license.

4. *License denial.* The board shall refuse to issue an outsourcing facility license for failure to meet the requirements of subsection 1. The board may refuse to issue or renew a license for any grounds under which the board may impose discipline. License or renewal denials shall be considered contested cases governed by chapter 17A.

5. *Discipline.* The board may fine, suspend, revoke, or impose other disciplinary sanctions on an outsourcing facility license for any of the following:

a. Any violation of the federal Food, Drug, and Cosmetic Act or federal regulations promulgated under the Act. A warning letter issued by the United States food and drug administration shall be conclusive evidence of a violation.

b. 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.

c. Refusing access to the outsourcing facility or facility records to an agent of the board for the purpose of conducting an inspection or investigation.

d. Any violation of this chapter or chapter 124, 124B, 126, or 205, or rule of the board.

2016 Acts, ch 1093, §5; 2018 Acts, ch 1026, §57; 2021 Acts, ch 68, §6