CHAPTER 1093

REGULATION OF PHARMACIES, PHARMACISTS, AND OUTSOURCING FACILITIES

S.F. 453

AN ACT relating to the board of pharmacy, including nonresident pharmacy and outsourcing facility licensure, pharmacist supervision of pharmacy technicians, alternate board members, and enforcement authority.

Be It Enacted by the General Assembly of the State of Iowa:

Section 1. Section 147.107, subsection 2, paragraph a, Code 2016, is amended to read as follows:

a. A pharmacist, physician, dentist, or podiatric physician who dispenses prescription drugs, including but not limited to controlled substances, for human use, may delegate nonjudgmental dispensing functions to staff assistants only when verification of the accuracy and completeness of the dispensing is determined by the pharmacist or practitioner in the pharmacist's or practitioner's physical presence. However, the physical presence requirement does not apply when a pharmacist or practitioner is utilizing an automated dispensing system; ~~or~~ when a pharmacist is utilizing a tech-check-tech program, as defined in section 155A.3; or when a pharmacist is remotely supervising a certified pharmacy technician practicing at a telepharmacy site approved by the board of pharmacy. When using an automated dispensing system the pharmacist or practitioner shall utilize an internal quality control assurance plan that ensures accuracy for dispensing. When using a tech-check-tech program or when remotely supervising a certified pharmacy technician practicing at an approved telepharmacy site, the pharmacist shall utilize an internal quality control assurance plan, in accordance with rules adopted by the board of pharmacy, that ensures accuracy for dispensing. Verification of automated dispensing, ~~and~~ tech-check-tech, and telepharmacy practice accuracy and completeness remains the responsibility of the pharmacist or practitioner and shall be determined in accordance with rules adopted by the board of pharmacy, the board of medicine, the dental board, and the board of podiatry for their respective licensees.

Sec. 2. Section 155A.3, Code 2016, is amended by adding the following new subsections:

NEW SUBSECTION. 24A. "*Managing pharmacy*" means a licensed pharmacy that oversees the activities of a telepharmacy site.

NEW SUBSECTION. 40A. "*Telepharmacy*" means the practice of pharmacy via telecommunications as provided by the board by rule.

NEW SUBSECTION. 40B. "*Telepharmacy site*" means a licensed pharmacy that is operated by a managing pharmacy and staffed by one or more qualified certified pharmacy technicians where pharmaceutical care services, including the storage and dispensing of prescription drugs, drug regimen review, and patient counseling, are provided by a licensed pharmacist through the use of technology.

Sec. 3. Section 155A.13, subsection 3, Code 2016, is amended to read as follows:

3. *a.* The board may issue a special or limited-use pharmacy license based upon special conditions of use imposed pursuant to rules adopted by the board for cases in which the board determines that certain requirements may be waived.

b. The board shall adopt rules for the issuance of a special or limited-use pharmacy license to a telepharmacy site. The rules shall address:

(1) Requirements for establishment and operation of a telepharmacy site, including but not limited to physical requirements and required policies and procedures.

(2) Requirements for being a managing pharmacy.

(3) Requirements governing operating agreements between telepharmacy sites and managing pharmacies.

(4) Training and experience required for certified pharmacy technicians working at a telepharmacy site.

(5) Requirements for a pharmacist providing services to and supervising a telepharmacy site.

(6) Any other health and safety concerns associated with a telepharmacy site.

c. The board shall not issue a special or limited-use pharmacy license to a proposed telepharmacy site if a licensed pharmacy that dispenses prescription drugs to outpatients is located within ten miles by the shortest driving distance of the proposed telepharmacy site unless the proposed telepharmacy site is located on property owned, operated, or leased by the state or unless the proposed telepharmacy site is located within a hospital campus and is limited to inpatient dispensing. The mileage requirement does not apply to a telepharmacy site that has been approved by the board and is operating as a telepharmacy prior to July 1, 2016.

d. An applicant seeking a special or limited-use pharmacy licensed for a proposed telepharmacy site that does not meet the mileage requirement established in paragraph "c" and is not statutorily exempt from the mileage requirement may apply to the board for a waiver of the mileage requirement. A waiver request shall only be granted if the applicant can demonstrate to the board that the proposed telepharmacy site is located in an area where there is limited access to pharmacy services and can establish the existence of compelling circumstances that justify waiving the mileage requirement. The board's decision to grant or deny a waiver request shall be a proposed decision subject to mandatory review by the director of the department of public health. The director shall review a proposed decision and shall have the power to approve, modify, or veto a proposed decision. The director's decision on a waiver request shall be considered final agency action subject to judicial review under chapter 17A. [1]

e. The board shall issue a special or limited-use pharmacy license to a telepharmacy site that meets the minimum requirements established by the board by rule.

Sec. 4. Section 155A.13A, Code 2016, is amended to read as follows:

155A.13A Nonresident pharmacy license — required, renewal, discipline.

1. *License required.* A pharmacy located outside of this state ~~which~~ that delivers, dispenses, or distributes by any method, prescription drugs or devices to an ultimate user in this state shall obtain a nonresident pharmacy license from the board. The board shall make available an application form for a nonresident pharmacy license and shall require such information it deems necessary to fulfill the purposes of this section. A nonresident pharmacy shall do all of the following in order to obtain a nonresident pharmacy license from the board:

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

b. Submit evidence of possession of a valid pharmacy license, permit, or registration ~~as a pharmacy in compliance with the laws of the state in which it is located, a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located, and evidence of compliance with all legal directions and requests for information issued by the regulatory or licensing agency of the state in which it is located~~ issued by the home state licensing authority.

c. (1) ~~Submit a list of the names, titles, and locations of all principal owners, partners, or officers of the nonresident pharmacy, all pharmacists employed by the nonresident pharmacy who deliver, dispense, or distribute by any method prescription drugs to an ultimate user in this state, and of the pharmacist in charge of the nonresident pharmacy. A nonresident pharmacy shall update the list within thirty days of any addition, deletion, or other change to the list.~~ Submit an inspection report that satisfies all of the following requirements:

(a) Less than two years have passed since the date of inspection.

(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.

[1] See chapter 1138, §22 herein

(e) The inspection report is the most recent report available that satisfies the requirements of this paragraph "c".

(2) If the home state licensing authority has not conducted an inspection satisfying the requirements of this paragraph "c", the pharmacy may submit an inspection report from the national association of boards of pharmacy's verified pharmacy program, or the pharmacy may submit an inspection report from another qualified entity if preapproved by the board, if the inspection report satisfies all of the other requirements of this paragraph "c".

(3) The board may recover from a nonresident pharmacy, prior to the issuance of a license or renewal, the costs associated with conducting an inspection by or on behalf of the board for purposes of satisfying the requirement in subparagraph (1), subparagraph division (d). In addition, the nonresident pharmacy shall submit evidence of corrective actions for all deficiencies noted in the inspection report and shall submit evidence of compliance with all legal directives of the home state regulatory or licensing authority.

d. Submit evidence that the nonresident pharmacy maintains records of the controlled substances delivered, dispensed, or distributed to ultimate users in this state.

e. Submit evidence that the nonresident pharmacy provides~~, during its regular hours of operation for at least six days and for at least forty hours per week,~~ a toll-free telephone service ~~to facilitate communication between ultimate users in this state and~~, the telephone number of which is printed on the label affixed to each prescription dispensed or distributed in Iowa, that allows patients to speak with a pharmacist who has access to ~~the ultimate user's~~ patient records ~~in the nonresident pharmacy, and that the toll-free number is printed on the label affixed to each container of prescription drugs delivered, dispensed, or distributed in this state~~ at least six days per week for a total of at least forty hours.

2. *Pharmacist license requirement.* The pharmacist who is the pharmacist in charge of the nonresident pharmacy shall be designated as such on the nonresident pharmacy license application or renewal. Any change in the pharmacist in charge shall be reported to the board within ten days of the change. The pharmacist in charge must be registered, not licensed, according to rules established by the board of pharmacy.

~~2.~~ 3. *License renewal.* A nonresident pharmacy shall renew its license on or before January 1 annually. In order to renew a nonresident pharmacy license, a nonresident pharmacy shall submit a ~~renewal~~ completed application and fee as determined by the board, and shall fulfill all of the requirements of subsection 1~~, paragraphs "b" through "e"~~. A nonresident pharmacy shall pay an additional fee for late renewal as determined by the board.

4. *License denial.* The board shall refuse to issue a nonresident pharmacy 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.

~~3.~~ 5. *Discipline.* The board may ~~deny~~ fine, suspend, ~~or~~ revoke, or impose other disciplinary sanctions on a nonresident pharmacy license for any ~~violation of this section, section 155A.15, subsection 2, paragraph "a", "b", "d", "e", "f", "g", "h", or "i", chapter 124, 124A, 124B, 126, or 205, or a rule of the board.~~ 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 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.

c. Refusing access to the pharmacy or pharmacy 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, 124A, 124B, 126, or 205, or rule of the board.

Sec. 5. NEW SECTION. **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.

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, 124A, 124B, 126, or 205, or rule of the board.

Sec. 6. Section 155A.26, subsections 2, 3, and 4, Code 2016, are amended to read as follows:

2. Make audits of the supply and inventory of controlled substances and prescription drugs in the possession of any and all individuals or institutions authorized to have possession of any controlled substances or prescription drugs, regardless of the location of the individual or institution.

3. Conduct routine and unannounced inspections of pharmacies, drug wholesalers, and the offices or business locations of all individuals and institutions authorized to have possession of prescription drugs including controlled substances or prescription devices, regardless of the location of the office or business.

4. Conduct inspections and investigations related to the practice of pharmacy and the distribution of prescription drugs and devices in and into this state.

Sec. 7. Section 155A.33, Code 2016, is amended to read as follows:

155A.33 Delegation of technical functions.

A pharmacist may delegate technical dispensing functions to pharmacy technicians, but only if the pharmacist is physically present to verify the accuracy and completeness of the patient's prescription prior to the delivery of the prescription to the patient or the patient's representative. However, the physical presence requirement does not apply when a pharmacist is utilizing an automated dispensing system or a tech-check-tech program or when a pharmacist is remotely supervising a certified pharmacy technician practicing at a telepharmacy site approved by the board. When using an automated dispensing system or a tech-check-tech program, or when remotely supervising a certified pharmacy technician practicing at an approved telepharmacy site, the pharmacist shall utilize an internal quality control assurance plan that ensures accuracy for dispensing. Verification of automated dispensing, ~~and~~ tech-check-tech, and telepharmacy practice accuracy and completeness remains the responsibility of the pharmacist and shall be determined in accordance with rules adopted by the board.

Sec. 8. NEW SECTION. **155A.45 Inspection reports — disclosure.**

Notwithstanding section 272C.6, subsection 4, paragraph "*a*", an inspection report in possession of the board, regardless of whether the report is based on a routine inspection or an inspection prompted by one or more complaints, may be disclosed to the national association of boards of pharmacy's inspection network.

Approved April 21, 2016