CHAPTER 1141

REGULATION OF PHARMACY AND WHOLESALE DISTRIBUTION OF DRUGS AND DEVICES

S.F. 2298

AN ACT relating to pharmacy regulation, including the composition of the board of pharmacy and the wholesale distribution of prescription drugs and devices, and including penalties.

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

Section 1. Section 147.14, subsection 1, paragraph e, Code 2018, is amended to read as follows:

e. For pharmacy, five members licensed to practice pharmacy, one member registered as a certified pharmacy technician as defined by the board by rule, and two members who are not licensed to practice pharmacy or registered as a certified pharmacy technician and who shall represent the general public.

Sec. 2. Section 155A.3, subsection 11, Code 2018, is amended to read as follows:

11. *"Device"* means ~~an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory,~~ a medical device, as classified by the United States food and drug administration, intended for use by a patient that is required ~~under federal or state law~~ by the United States food and drug administration to be ordered or prescribed for a patient by a practitioner.

Sec. 3. Section 155A.3, subsection 14, Code 2018, is amended by striking the subsection.

Sec. 4. Section 155A.3, subsection 25, Code 2018, is amended to read as follows:

25. *"Limited ~~drug and device~~ distributor"* means a person operating or maintaining~~, either within or outside this state,~~ a location ~~at which limited noncontrolled~~, regardless of the location, where prescription drugs~~, prescription~~ or devices~~, and medical gases,~~ are distributed ~~to patients in this state pursuant to a prescription drug order; or a person operating or maintaining a location at which limited quantities of drugs, devices, or medical gases are distributed~~ at wholesale ~~in this state~~ or to a patient pursuant to a prescription drug order, who is not eligible for a wholesale distributor license or pharmacy license. ~~A *"limited drug and device distributor"* does not include a pharmacy licensed pursuant to this chapter or a drug wholesaler providing prescription drugs to patients in this state pursuant to a drug manufacturer's prescription drug assistance program.~~

Sec. 5. Section 155A.3, subsection 26, Code 2018, is amended by striking the subsection.

Sec. 6. Section 155A.3, Code 2018, is amended by adding the following new subsections:

NEW SUBSECTION. 27A. *"Manufacturer"* means manufacturer as defined by the federal Drug Supply Chain Security Act, 21 U.S.C. §360eee et seq.

NEW SUBSECTION. 27B. *"Medical convenience kit"* means a collection of devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or ultimate user.

NEW SUBSECTION. 41A. *"Product"* means the same as defined in 21 U.S.C. §360eee.

NEW SUBSECTION. 42A. *"Repackager"* means a person who owns or operates an establishment that repackages or relabels a product or package for further sale or for distribution without a further transaction.

NEW SUBSECTION. 45A. *"Third-party logistics provider"* means an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product nor have responsibility to direct the sale or other disposition of the product.

Sec. 7. Section 155A.3, subsection 40, Code 2018, is amended by striking the subsection and inserting in lieu thereof the following:

40. *"Prescription drug"* or *"drug"* means a drug, as classified by the United States food and drug administration, that is required by the United States food and drug administration to be prescribed or administered to a patient by a practitioner prior to dispensation.

Sec. 8. Section 155A.3, subsection 48, Code 2018, is amended by striking the subsection and inserting in lieu thereof the following:

48. *"Wholesale distribution"* means the distribution of a drug to a person other than a consumer or patient, or the receipt of a drug by a person other than a consumer or patient, but does not include any of the following:

a. Intracompany distribution of any drug between members of an affiliate, as defined in 21 U.S.C. §360eee, or within a manufacturer.

b. The distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities under common control.

c. The distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration as defined in 42 U.S.C. §247d, except that for purposes of this paragraph a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason.

d. The dispensing of a drug pursuant to a prescription drug order.

e. The distribution of minimal quantities of a drug by a pharmacy to a practitioner for office use.

f. The distribution of a drug or an offer to distribute a drug by a charitable organization to an affiliate, as defined in 21 U.S.C. §360eee, of the organization that is a nonprofit, to the extent otherwise permitted by law.

g. The purchase or other acquisition of a drug by a dispenser, as defined in 21 U.S.C. §360eee, hospital, or other health care entity for use by such dispenser, hospital, or other health care entity.

h. The distribution of a drug by the manufacturer of such drug.

i. The receipt or transfer of a drug by a third-party logistics provider, provided that such third-party logistics provider does not take ownership of the drug.

j. A common carrier that transports a drug, provided that the common carrier does not take ownership of the drug.

k. The distribution of a drug or an offer to distribute a drug by a repackager that has taken ownership or possession of the drug and repackages it.

l. The return of a saleable product when conducted by a dispenser.

m. The distribution of a medical convenience kit under any of the following circumstances:

(1) The medical convenience kit is assembled in an establishment registered with the United States food and drug administration as a device manufacturer.

(2) The medical convenience kit does not contain a controlled substance.

(3) In the case of a medical convenience kit that includes a product, the person that manufacturers the kit does all of the following:

(a) Purchases the product directly from a pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer.

(b) Does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor.

(4) In the case of a medical convenience kit that includes a product, the product is any of the following:

(a) An intravenous solution intended for the replenishment of fluids and electrolytes.

(b) Intended to maintain the equilibrium of water and minerals in the body.

(c) Intended for irrigation or reconstitution.

(d) An anesthetic.

(e) An anticoagulant.

(f) A vasopressor.

(g) A sympathomimetic.

n. The distribution of an intravenous drug that by its formulation is intended for the replenishment of fluids and electrolytes such as sodium, chloride, and potassium, or calories such as dextrose and amino acids.

o. The distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body such as a dialysis solution.

p. The distribution of a drug intended for irrigation or sterile water intended for irrigation or for injection.

q. The distribution of a medical gas.

r. The facilitation of the distribution of a product by providing administrative services, including the processing of orders and payments.

s. The transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager for the purpose of repackaging the product for use by that hospital or other health care entity under common control, if the ownership of the product remains with the hospital or other health care entity at all times.

Sec. 9. Section 155A.3, subsection 49, Code 2018, is amended by striking the subsection and inserting in lieu thereof the following:

49. *"Wholesale distributor"* means a person, other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager, engaged in the wholesale distribution of a drug.

Sec. 10. Section 155A.4, subsection 2, paragraph a, Code 2018, is amended to read as follows:

a. A ~~wholesaler~~ limited distributor, third-party logistics provider, or wholesale distributor to distribute prescription drugs or devices as provided by state or federal law.

Sec. 11. Section 155A.4, subsection 2, paragraph h, Code 2018, is amended by striking the paragraph.

Sec. 12. Section 155A.5, Code 2018, is amended to read as follows:

155A.5 Injunction.

Notwithstanding the existence or pursuit of any other remedy the board may, in the manner provided by law, maintain an action in the name of the state for injunction or other process against any person to restrain or prevent the establishment, conduct, management, or operation of a pharmacy ~~or wholesaler~~, limited distributor, third-party logistics provider, or wholesale distributor without a license, or to prevent the violation of provisions of this chapter. Upon request of the board, the attorney general shall institute the proper proceedings and the county attorney, at the request of the attorney general, shall appear and prosecute the action when brought in the county attorney's county.

Sec. 13. Section 155A.17, Code 2018, is amended by striking the section and inserting in lieu thereof the following:

155A.17 Wholesale distributor license.

1. A person shall not engage in wholesale distribution without a wholesale distributor license.

2. Wholesale distributors shall comply with the national standards contained in the federal Drug Supply Chain Security Act, 21 U.S.C. §360eee et seq., and national standards promulgated thereunder.

3. The board shall adopt rules establishing requirements for wholesale distributor licenses, licensure fees, and other relevant matters consistent with the federal Drug Supply Chain Security Act, 21 U.S.C. §360eee et seq.

4. The board may deny, suspend, or revoke a wholesale distributor license, or otherwise discipline a wholesale distributor, for failure to meet the applicable standards or for a violation of the laws of this state, another state, or the United States, or for a violation of this chapter, chapter 124, 124B, 126, or 205, or a rule of the board.

Sec. 14. NEW SECTION. **155A.17A Third-party logistics provider license.**

1. A person shall not operate as a third-party logistics provider in this state without a third-party logistics provider license.

2. Third-party logistics providers shall comply with national standards contained in the federal Drug Supply Chain Security Act, 21 U.S.C. §360eee et seq., and national standards promulgated thereunder.

3. The board shall adopt rules establishing requirements for a third-party logistics provider license, licensure fees, and other relevant matters consistent with the federal Drug Supply Chain Security Act, 21 U.S.C. §360eee et seq.

4. The board may deny, suspend, or revoke a third-party logistics provider license, or otherwise discipline a third-party logistics provider, for failure to meet the applicable standards or for a violation of the laws of this state, another state, or the United States, or for a violation of this chapter, chapter 124, 124B, 126, or 205, or a rule of the board.

Sec. 15. Section 155A.42, Code 2018, is amended to read as follows:

155A.42 Limited ~~drug and device~~ distributor license.

1. A person other than a wholesale distributor, licensed pharmacy, or practitioner, shall not ~~act as a limited drug and device distributor~~ engage in any of the following activities in this state without a limited distributor license~~. The license shall be identified as a limited drug and device distributor license.~~:

a. Distribution of a medical gas or device at wholesale or to a patient pursuant to a prescription drug order.

b. Wholesale distribution of a prescription animal drug.

c. Wholesale distribution of a prescription drug, or brokering the distribution of a prescription drug at wholesale, by a manufacturer, a manufacturer's co-licensed partner, or a repackager.

d. Intracompany distribution of a prescription drug, including pharmacy chain distribution centers.

e. Distribution at wholesale of a combination product as defined by the United States food and drug administration, medical convenience kit, intravenous fluid or electrolyte, dialysis solution, radioactive drug, or irrigation or sterile water solution to be dispensed by prescription only.

f. Distribution of a dialysis solution by the manufacturer or the manufacturer's agent to a patient pursuant to a prescription drug order, provided that a licensed pharmacy processes the prescription drug order.

2. The board shall ~~establish, by rule,~~ adopt rules establishing the requirements for a limited distributor license, licensure fees, compliance standards ~~for limited drug and device distributors and may define specific types of limited drug and device distributors~~, and any other relevant matters. ~~The board may identify, by rule, specific prescription drugs or classes of noncontrolled prescription drugs, which may be distributed by a limited drug and device distributor.~~ A limited distributor shall not be required to have an onsite pharmacist.

~~3. The board shall adopt rules pursuant to chapter 17A relating to the issuance of a limited drug and device distributor license. The rules shall provide for conditions of licensure, compliance standards, licensure fees, disciplinary action, and other relevant matters.~~

~~4.~~ 3. The board may deny, suspend, or revoke a limited ~~drug and device~~ distributor's license, or otherwise discipline a limited distributor, for failure to meet the applicable standards or for a violation of the laws of this state, another state, or the United States ~~relating to prescription drugs or controlled substances~~, or for a violation of this chapter, chapter 124, 124B, 126, or 205, ~~or 272C,~~ or a rule of the board.

Approved May 16, 2018