An Act relating to wholesale distribution of drugs in accordance with federal statue and limited distribution of drugs for entities other than wholesalers.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section1. Section 155A.3, subsection 10, Code 2017, is amended to read as follows:

10. "*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 FDA, intended for use by a patient that is required ~~under federal or state law~~ by the FDA to be ordered or prescribed to a patient by a practitioner.

Sec. 2. Section 155A.3, subsection 13, Code 2017, is amended by striking the subsection.

Sec. 3. Section 155A.3, subsection 23, Code 2017, is amended to read as follows:

23. "*Limited ~~drug and device~~ distributor*" means a person operating or maintaining~~, either within or outside this state,~~ a location, regardless of location, ~~at~~ in which ~~limited noncontrolled~~ 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. 4. Section 155A.3, subsection 24, Code 2017, is amended to read as follows:

24. "~~*Logistics*~~ *Third-party logistics provider"* or *"3PL"* means an entity that provides or coordinates warehousing~~, distribution,~~ or other logistics services of a product in interstate commerce on behalf of a manufacturer ~~or other owner of a drug~~, wholesale distributor, or dispenser of a product, but does not take ~~title to~~ ownership of the ~~drug or~~ product nor have ~~general~~ responsibility to direct ~~its~~ the sale or ~~other~~ disposition of the product.

Sec. 5. Section 155A.3, subsection 38, Code 2017, is amended to read as follows:

38. *"Prescription drug"* or *"drug"* means ~~any of the following:~~

~~a. A substance for which federal or state law requires a prescription before it may be legally dispensed to the public.~~

~~b. A drug or device that under federal law is required, prior to being dispensed, or delivered, to be labeled with one of the following statements:~~

~~1. Caution: Federal law prohibits dispensing without a prescription.~~

~~2. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.~~

~~3. Caution: Federal law restricts this device to sale by, or on the order of, a physician.~~

~~4. Rx only.~~

c. ~~A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only, or is restricted to use by a practitioner only.~~ a drug, as classified by the FDA, that is required by the FDA to be prescribed or administered to a patient by a practitioner.

Sec. 6. Section 155A.3, subsection 46, Code 2017, is amended to read as follows:

46. "~~*Wholesaler*~~ *Wholesale distributor*" means a person ~~operating or maintaining, either within or outside this state, a manufacturing plant, wholesale distribution center, wholesale business, or any other business in which prescription drugs or devices, medicinal chemicals, medicines, or poisons are sold, manufactured, compounded, dispensed, stocked, exposed, distributed from, or offered for sale at wholesale in this state~~ other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager engaged in wholesale distribution. ~~"*Wholesaler*" does not include those wholesalers who sell only proprietary or other-the-counter medicines. "*Wholesaler*" also does not include a commercial carrier that temporarily stores prescription drugs or devices, medicinal chemicals, medicines, or poisons while in transit.~~

Sec. 7. Section 155A.3, subsection 47, Code 2017, is amended by striking the subsection.

Sec. 8. Section 155A.3, Code 2017, is amended by adding the following new subsection:

NEW SUBSECTION: *"DSCSA"* means the Drug Supply Chain Security Act as included as Part II of the Federal Drug Quality and Security Act of 2013.

Sec. 9. Section 155A.3, Code 2017, is amended by adding the following new subsection:

NEW SUBSECTION: "*FDA"* means the United States Food and Drug Administration.

Sec. 10. Section 155A.3, Code 2017, is amended by adding the following new subsection:

NEW SUBSECTION: "*Manufacturer"* means manufacturer as it is defined by the DSCSA.

Sec. 11. Section 155A.3, Code 2017, is amended by adding the following new subsection:

NEW SUBSECTION: "*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.

Sec. 12. Section 155A.3, Code 2017, is amended by adding the following new subsection:

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

1. intracompany distribution of any drug between members of an affiliate or within a manufacturer;
2. the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;
3. the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
4. the dispensing of a drug pursuant to a prescription;
5. the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

6. the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
7. the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;
8. the distribution of a drug by the manufacturer of such drug;
9. the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;
10. a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;
11. the distribution of a drug or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repackages it;
12. salable drug returns when conducted by a dispenser;
13. the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a "medical convenience kit") if—
    a. the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer;
    b. the medical convenience kit does not contain a controlled substance;
    c. in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—
        1. purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and
        2. does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and
    d. in the case of a medical convenience kit that includes a product, the product is—

1. an intravenous solution intended for the replenishment of fluids and electrolytes;
2. a product intended to maintain the equilibrium of water and minerals in the body;
3. a product intended for irrigation or reconstitution;
4. an anesthetic;
5. an anticoagulant;
6. a vasopressor; or
7. a sympathomimetic;

14. 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);
15. the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
16. the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;
17. the distribution of a medical gas;
18. facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or
19. 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 drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

Sec. 13. Section 155A.4, subsection 2, paragraph a, Code 2017, is amended to read as follows:

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

Sec. 14. Section 155A.4, subsection 2, paragraph h, Code 2017, is amended by striking the paragraph.

Sec. 15. Section 155A.5, Code 2017, is amended to read as follows:

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,~~ wholesale distributor, third-party logistics provider, or limited distributor without 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. 16. Section 155A.17, Code 2017, is amended to read as follows:

1. A person shall not ~~establish, conduct, or maintain a wholesale drug business as defined in this chapter~~ engage in wholesale distribution without a wholesale distributor license. ~~The license shall be identified as a wholesale drug license.~~
2. ~~The board shall establish standards for drug wholesaler licensure and may define specific types of wholesaler licenses. The board may deny, suspend, or revoke a drug wholesale license 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, devices, or controlled substances, or for a violation of this chapter, chapter 124, 124A, 124B, 126, or 205, or a rule of the board.~~ The national standards for wholesale distributors created by the DSCSA and regulations promulgated thereunder are effective.
3. The board shall adopt rules ~~pursuant to chapter 17A on matters pertaining to the issuance of~~ establishing the requirements for a wholesale ~~drug~~ distributor license, application fees, and any other matters allowed by the DSCSA. ~~The rules shall provide for conditions of licensure, compliance standards, licensure fees, disciplinary action, and other relevant matters. Additionally, the rules shall establish provisions or exceptions for pharmacies, chain pharmacy distribution centers, logistics providers, and other types of wholesalers relating to pedigree requirements, drug or device returns, and other related matters, so as not to prevent or interfere with usual, customary, and necessary business activities.~~

4. ~~This section does not apply to a manufacturer's representative acting in the usual course of business or employment as a manufacturer's representative.~~ The board may deny, suspend, revoke, or otherwise discipline a wholesale distributor license 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, 205, or a rule of the board.

Sec. 17. NEW SECTION. **155A.17A 3PL license.**

1. A person shall not operate as a third-party logistics provider in this state without a 3PL license.

2. The national standards for third-party logistics providers created by the DSCSA and regulations promulgated thereunder are effective.

3. The board shall adopt rules establishing the requirements for a 3PL license, application fees, and any other matters allowed by the DSCSA.

4. The board may deny, suspend, revoke, or otherwise discipline a 3PL license 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, 205, or a rule of the board.

Sec. 18. Section 155A.42, Code 2017, is amended to read as follows:

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

1. A person other than a wholesale distributor or pharmacy licensed by the board, or a 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 order.

b. Distribution at wholesale of a prescription animal drug.

c. Distribution at wholesale 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 prescription drugs, including chain pharmacy distribution centers.

e. Distribution at wholesale of a combination product, medical convenience kit, intravenous fluid or electrolyte, dialysis solution, radioactive drug, or irrigation or sterile water solution that is designated as 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,~~ shall adopt rules establishing the requirements for a limited distributor license, application 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.~~ The board may deny, suspend, ~~or~~ revoke, or otherwise discipline a limited ~~drug and device distributor's~~ distributor license 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, ~~124A,~~ 124B, 126, ~~or~~ 205, ~~or 272C,~~ or a rule of the board.

EXPLANATION

The United States Congress enacted the Drug Quality and Security Act in 2013. Part II of the Act was the Drug Supply Chain Security Act which created new standards in the distribution chain of drug products to ensure product quality. This bill updates Iowa Code to be in compliance with the federal DSCSA, which contains a provision that prohibits states from enacting laws that are more or less strict than DSCSA. The board currently licenses many types of drug distributors under a single "Wholesaler Distributor" license. Under DSCSA, entities engaging in the wholesale distribution of prescription drugs are held to a higher minimum standard than entities

engaged in exempted distribution activities. This bill creates specific license categories for Third-Party Logistics providers and Limited Distributors to shield entities exempt from DSCSA from the standards required of wholesale distributors under federal law.