

Senate File 2298 - Introduced

SENATE FILE 2298
BY COMMITTEE ON HUMAN
RESOURCES

(SUCCESSOR TO SSB 3072)

A BILL FOR

1 An Act relating to pharmacy regulation, including the
2 composition of the board of pharmacy and the wholesale
3 distribution of prescription drugs and devices, and
4 including penalties.

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

1 Section 1. Section 147.14, subsection 1, paragraph e, Code
2 2018, is amended to read as follows:

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

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

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

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

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

22 25. ~~"Limited drug and device distributor" means a person~~
23 ~~operating or maintaining, either within or outside this state,~~
24 ~~a location at which limited noncontrolled, regardless of the~~
25 ~~location, where prescription drugs, prescription or devices,~~
26 ~~and medical gases, are distributed to patients in this state~~
27 ~~pursuant to a prescription drug order; or a person operating or~~
28 ~~maintaining a location at which limited quantities of drugs,~~
29 ~~devices, or medical gases are distributed at wholesale in this~~
30 ~~state or to a patient pursuant to a prescription drug order,~~
31 who is not eligible for a wholesale distributor license or
32 pharmacy license. A "limited drug and device distributor" does
33 not include a pharmacy licensed pursuant to [this chapter](#) or a
34 drug wholesaler providing prescription drugs to patients in
35 this state pursuant to a drug manufacturer's prescription drug

1 ~~assistance program.~~

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

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

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

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

13 NEW SUBSECTION. 41A. "*Product*" means the same as defined in
14 21 U.S.C. §360eee.

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

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

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

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

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

1 following:

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

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

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

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

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

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

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

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

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

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

35 j. A common carrier that transports a drug, provided that

1 the common carrier does not take ownership of the drug.

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

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

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

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

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

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

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

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

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

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

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

29 (c) Intended for irrigation or reconstitution.

30 (d) An anesthetic.

31 (e) An anticoagulant.

32 (f) A vasopressor.

33 (g) A sympathomimetic.

34 *n.* The distribution of an intravenous drug that by its
35 formulation is intended for the replenishment of fluids and

1 electrolytes such as sodium, chloride, and potassium, or
2 calories such as dextrose and amino acids.

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

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

8 q. The distribution of a medical gas.

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

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

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

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

26 Sec. 10. Section 155A.4, subsection 2, paragraph a, Code
27 2018, is amended to read as follows:

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

31 Sec. 11. Section 155A.4, subsection 2, paragraph h, Code
32 2018, is amended by striking the paragraph.

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

35 **155A.5 Injunction.**

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

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

15 **155A.17 Wholesale distributor license.**

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

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

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

26 4. The board may deny, suspend, or revoke a wholesale
27 distributor license, or otherwise discipline a wholesale
28 distributor, for failure to meet the applicable standards or
29 for a violation of the laws of this state, another state, or
30 the United States, or for a violation of this chapter, chapter
31 124, 124B, 126, or 205, or a rule of the board.

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

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

1 license.

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

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

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

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

19 **155A.42 Limited ~~drug and device~~ distributor license.**

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

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

28 b. Wholesale distribution of a prescription animal drug.

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

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

35 e. Distribution at wholesale of a combination product as

1 defined by the United States food and drug administration,
2 medical convenience kit, intravenous fluid or electrolyte,
3 dialysis solution, radioactive drug, or irrigation or sterile
4 water solution to be dispensed by prescription only.

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

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

19 3. ~~The board shall adopt rules pursuant to chapter~~
20 ~~17A relating to the issuance of a limited drug and device~~
21 ~~distributor license. The rules shall provide for conditions of~~
22 ~~licensure, compliance standards, licensure fees, disciplinary~~
23 ~~action, and other relevant matters.~~

24 4. ~~3.~~ The board may deny, suspend, or revoke a limited
25 drug and device distributor's license, or otherwise discipline
26 a limited distributor, for failure to meet the applicable
27 standards or for a violation of the laws of this state, another
28 state, or the United States relating to prescription drugs or
29 controlled substances, or for a violation of this chapter,
30 chapter 124, 124B, 126, or 205, or 272C, or a rule of the board.

31 EXPLANATION

32 The inclusion of this explanation does not constitute agreement with
33 the explanation's substance by the members of the general assembly.

34 This bill relates to pharmacy regulation by modifying the
35 composition of the board of pharmacy and altering the laws

1 governing the wholesale distribution of drugs.

2 The bill modifies the composition of the board of pharmacy by
3 adding a registered, certified pharmacy technician as a member
4 of the board.

5 The bill also alters the laws governing the wholesale
6 distribution of drugs. Congress enacted the federal Drug
7 Quality and Security Act (DQSA) in 2013. Title II of the
8 DQSA included the federal Drug Supply Chain Security Act
9 (DSCSA) which created new standards for the distribution of
10 prescription drugs and devices, including prescription drugs
11 defined as products under the DSCSA, to ensure prescription
12 drug and device quality. The bill updates Code chapter 155A
13 to be in compliance with the DSCSA, which also contains a
14 provision that prohibits states from enacting laws that are
15 more or less strict than the DSCSA.

16 The board of pharmacy currently licenses many types of drug
17 distributors under a single wholesale distributor license.
18 Under the DSCSA, entities engaged in the wholesale distribution
19 of prescription drugs are held to a higher minimum standard
20 than entities engaged in other drug distribution activities.
21 The bill creates specific license categories for third-party
22 logistics providers, limited distributors, and wholesale
23 distributors to shield entities exempt from DSCSA from the
24 standards required of wholesale distributors under federal
25 law. The bill grants the board authority to deny, suspend,
26 or revoke licenses for third-party logistics providers,
27 limited distributors, and wholesale distributors, or otherwise
28 discipline such providers, limited distributors, and wholesale
29 distributors.