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Short Title: Wholesale Drug Distribution License.

(Public)

Sponsors:

Referred to:

April 19, 1991

A BILL TO BE ENTITLED
AN ACT TO LICENSE WHOLESALE DRUG DISTRIBUTORS.

Whereas, the Congress of the United States passed Public Law 100-293, the Prescription Drug Marketing Act of 1987, part of which will prohibit wholesale drug distributors from distributing prescription drugs in interstate commerce after September 14, 1992, in a state unless that person is licensed by the state; and

Whereas, the State licensing program must meet certain guidelines established by the United States Secretary of Health and Human Services (21 C.F.R. Part 205); and

Whereas, if the State fails to enact a licensing program that meets these federal guidelines, it will be a violation of federal law to engage in the wholesale distribution of prescription drugs in interstate commerce in North Carolina; and

Whereas, there is no provision for federal licensing if the State fails to act;

Now, therefore,

The General Assembly of North Carolina enacts:

Section 1. Title. This act shall be known as the "Wholesale Drug Distributor Licensing Act of 1991."

Sec. 2. Chapter 106 of the General Statutes is amended by adding a new Article to read:

"ARTICLE 12A.**"WHOLESALE PRESCRIPTION DRUG DISTRIBUTORS.****"§ 106-145.1. Purpose and interpretation of Article.**

This Article establishes a State licensing program for wholesale distributors to enable wholesale distributors to comply with federal law. This Article shall be construed to do only that required for compliance with 21 U.S.C. § 353(e) and 21 C.F.R. Part 205. This Article shall be interpreted to be consistent with 21 C.F.R. Part 205, Guidelines for State Licensing of Wholesale Prescription Drug Distributors. In the event of a conflict, the federal law controls.

"§ 106-145.2. Definitions.

The following definitions apply in this Article:

- (1) Blood. – Whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- (2) Blood component. – That part of blood separated by physical or mechanical means.
- (3) Commissioner. – The Commissioner of Agriculture.
- (4) Common control. – The power to direct or cause the direction of the management and policies of a person, whether by ownership of stock, by voting rights, by contract, or otherwise.
- (5) Department. – The Department of Agriculture.
- (6) Drug sample. – A unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.
- (7) Manufacturer. – A person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling a prescription drug.
- (8) Person. – An individual, a corporation, a partnership, or any other entity.
- (9) Prescription drug. – A human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to 21 U.S.C. § 353(b).
- (10) Wholesale distribution. – Distribution of a prescription drug to a person who is not a consumer or patient, other than any of the following types of distributions:
 - a. Intracompany sales. An intracompany sale is a transaction or transfer between any divisions, subsidiary and parent companies, or affiliated companies under common control of the same corporate entity.
 - b. The purchase or other acquisition of a prescription drug by a hospital or other health care entity that is a member of a group purchasing organization for its own use from the group purchasing organization or from other hospitals or other health care entities that are members of these organizations.
 - c. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable

1 organization described in section 501(c)(3) of the Internal
2 Revenue Code to a nonprofit affiliate of the organization to the
3 extent otherwise permitted by law.

4 d. The sale, purchase, or trade of a prescription drug or an offer to
5 sell, purchase, or trade a prescription drug among hospitals or
6 other health care entities that are under common control.

7 e. The sale, purchase, or trade of a prescription drug or an offer to
8 sell, purchase, or trade a prescription drug for emergency
9 medical reasons. Emergency medical reasons include transfers
10 of prescription drugs by a retail pharmacy to another retail
11 pharmacy to alleviate a temporary shortage when the gross
12 dollar value of the transfers does not exceed five percent (5%)
13 of the total prescription drug sales revenue of either the
14 transferor or transferee pharmacy during any 12-consecutive-
15 month period.

16 f. The sale, purchase, or trade of a prescription drug; an offer to
17 sell, purchase, or trade a prescription drug; or the dispensing of
18 a prescription drug pursuant to a prescription.

19 g. The distribution of drug samples by a representative of a
20 manufacturer or a wholesale distributor.

21 h. The sale, purchase, or trade of blood and blood components
22 intended for transfusion.

23 (11) Wholesale distributor. – A person who is engaged in the wholesale
24 distribution of prescription drugs. The term includes manufacturers,
25 repackers, own-label distributors, private-label distributors, jobbers,
26 brokers, warehouses, independent wholesale drug traders, and retail
27 pharmacies that conduct wholesale distributions. A warehouse
28 includes a warehouse of a manufacturer or wholesale distributor, a
29 chain drug warehouse, and a wholesale drug warehouse.

30 **"§ 106-145.3. Wholesale distributor must have license.**

31 (a) Requirement. – Every wholesale distributor engaged in the wholesale
32 distribution of prescription drugs in interstate commerce in this State shall obtain a
33 license from the Commissioner for each location from which prescription drugs are
34 distributed and shall renew each license annually. A license may cover multiple
35 buildings and multiple operations at a single location, at the wholesale distributor's
36 discretion. A license expires on December 31 of the year in which it is issued. A
37 wholesale distributor licensed under this section is not required to register under G.S.
38 106-140.1. In lieu of licensing under this section, a wholesale distributor who has no
39 facilities in this State may register under G.S. 106-140.1 if the wholesale distributor
40 possesses a valid license granted by another state that has requirements substantially
41 similar to this Article.

42 (b) Reciprocity. – The Commissioner may license an out-of-State wholesale
43 distributor on the basis of reciprocity with another state when the following conditions
44 apply:

1 (1) The out-of-State wholesale distributor possesses a valid license
2 granted by another state pursuant to requirements substantially
3 equivalent to the license requirements of this State.

4 (2) The other state extends reciprocal treatment under its own laws to
5 wholesale distributors licensed in this State.

6 **"§ 106-145.4. Application and fee for license.**

7 (a) Application. – An application for a wholesale distributor license or for
8 renewal of a wholesale distributor license shall be on a form prescribed by the
9 Commissioner and shall include the following information:

10 (1) The name, full business address, and telephone number of the
11 applicant.

12 (2) All trade or business names used by the applicant.

13 (3) Addresses, telephone numbers, and names of contact persons for all
14 facilities used by the applicant for the storage, handling, and
15 distribution of prescription drugs.

16 (4) The type of ownership or operation of the applicant, such as a
17 partnership, a corporation, or a sole proprietorship.

18 (5) The name of each owner and operator of the applicant, including:

19 a. If the applicant is an individual, the individual's name.

20 b. If the applicant is a partnership, the name of each partner and
21 the name of the partnership.

22 c. If the applicant is a corporation, the name and title of each
23 corporate officer and director, the corporate name of the
24 corporation, and the state of incorporation.

25 d. If the applicant is a sole proprietorship, the full name of the sole
26 proprietor and the name of the business entity.

27 (6) Any other information required by the Commissioner to determine if
28 the applicant is qualified to receive a license.

29 When a change occurs in any information listed in this subsection after a license is
30 issued, the license holder shall report the change to the Commissioner within 90 days
31 after the change.

32 (b) Fee. – An application for an initial license or a renewed license as a
33 wholesale distributor shall be accompanied by a nonrefundable fee of five hundred
34 dollars (\$500.00) for a manufacturer or three hundred fifty dollars (\$350.00) for any
35 other person.

36 **"§ 106-145.5. Review of application and qualifications of applicant.**

37 The Commissioner shall determine whether to issue or deny a wholesale distributor
38 license within 90 days after an applicant files an application for a license with the
39 Commissioner. In reviewing an application, the Commissioner shall consider the
40 factors listed in this subsection. In the case of a partnership or corporation, the
41 Commissioner shall consider the factors as applied to each individual whose name is
42 required to be included in the license application.

43 The factors to be considered are:

- 1 (1) Any convictions of the applicant under any federal, state, or local law
2 relating to drug samples, wholesale or retail drug distribution, or
3 distribution of controlled substances.
- 4 (2) Any felony convictions of the applicant under federal, state, or local
5 law.
- 6 (3) The applicant's past experience in the manufacture or distribution of
7 controlled substances and other prescription drugs.
- 8 (4) Whether the applicant has previously given any false or fraudulent
9 information in an application made in connection with drug
10 manufacturing or distribution.
- 11 (5) Suspension or revocation by the federal government or a state or local
12 government of any license currently or previously held by the
13 applicant for the manufacture or distribution of any controlled
14 substances or other prescription drugs.
- 15 (6) Compliance with the licensing requirements under any previously
16 granted license.
- 17 (7) Compliance with the requirements to maintain or make available to the
18 Commissioner or to a federal, state, or local law enforcement official
19 those records required under G.S. 106-145.8.
- 20 (8) Whether the applicant requires employees of the applicant who are
21 involved in any prescription drug wholesale distribution activity to
22 have education, training, experience, or any combination of these
23 factors sufficient to enable the employee to perform assigned functions
24 in a manner that ensures that prescription drug quality, safety, and
25 security will be maintained at all times as required by law.
- 26 (9) Any other factors or qualifications the Commissioner considers
27 relevant to and consistent with the public health and safety.

28 The Commissioner shall inspect the facility of an applicant at which prescription
29 drugs will be stored, handled, or distributed before issuing the applicant a license.

30 **"§ 106-145.6. Denial, revocation, and suspension of license; penalties for violations.**

31 (a) Adverse Action. – The Commissioner may deny a license to an applicant if
32 the Commissioner determines that granting the applicant a license would not be in the
33 public interest. Public interest considerations shall be limited to factors and
34 qualifications that are directly related to the protection of public health and safety. The
35 Commissioner may deny, suspend, or revoke a license for substantial or repeated
36 violations of this Article or for conviction of a violation of any other federal, state, or
37 local prescription drug law or regulation. Chapter 150B of the General Statutes governs
38 the denial, suspension, or revocation of a license under this Article.

39 (b) Criminal Sanctions. – It is unlawful to engage in wholesale distribution in this
40 State without a wholesale distributor license or to violate any other provision of this
41 Article. A person who violates this Article commits a Class H felony and is punishable
42 in accordance with G.S. 14-1.1. A fine imposed for a violation of this Article may not
43 exceed two hundred fifty thousand dollars (\$250,000).

1 (c) Civil Penalty. – The Commissioner may assess a civil penalty of not more
2 than ten thousand dollars (\$10,000) against a person who violates any provision of this
3 Article. In determining the amount of a civil penalty, the Commissioner shall consider
4 the degree and extent of harm caused by the violation. Chapter 150B of the General
5 Statutes governs the assessment of a civil penalty under this subsection. If a civil
6 penalty is not paid within 30 days after the completion of judicial review of a final
7 agency decision by the Commissioner, the penalty may be collected in any manner by
8 which a debt may be collected. Penalties collected shall be credited to the General Fund.

9 **§ 106-145.7. Storage, handling, and records of prescription drugs.**

10 (a) Facilities. – All facilities at which prescription drugs are stored, warehoused,
11 handled, held, offered, marketed, or displayed for wholesale distribution shall meet the
12 following requirements:

- 13 (1) Be of suitable size and construction to facilitate cleaning, maintenance,
14 and proper operations.
- 15 (2) Have storage areas designed to provide adequate lighting, ventilation,
16 temperature, sanitation, humidity, space, equipment, and security
17 conditions.
- 18 (3) Have a quarantine area for the storage of prescription drugs that are
19 outdated, damaged, deteriorated, misbranded, or adulterated, or that
20 are in immediate or sealed secondary containers that have been
21 opened.
- 22 (4) Be maintained in a clean and orderly condition.
- 23 (5) Be free from infestation by insects, rodents, birds, or vermin of any
24 kind.

25 (b) Security. – All facilities used for wholesale distribution shall be secure from
26 unauthorized entry. Access from outside the premises shall be kept to a minimum and
27 be well-controlled. The outside perimeter of the premises shall be well-lighted. Entry
28 into areas where prescription drugs are held shall be limited to authorized personnel.
29 The facilities shall be equipped with the following:

- 30 (1) An alarm system to detect entry after hours.
- 31 (2) A security system that will provide suitable protection against theft
32 and diversion. When appropriate, the security system shall provide
33 protection against theft or diversion that is facilitated or hidden by
34 tampering with computers or electronic records.

35 (c) Storage. – All prescription drugs for wholesale distribution shall be stored at
36 appropriate temperatures and under appropriate conditions in accordance with any
37 requirements stated in the labeling of the prescription drugs or with requirements in the
38 current edition of an official compendium, such as the United States
39 Pharmacopeia/National Formulary (USP/NF). If the labeling of a prescription drug or a
40 compendium do not establish storage requirements for a prescription drug, the drug may
41 be held at 'controlled' room temperature, as defined in an official compendium, to help
42 ensure that its identity, strength, quality, and purity are not adversely affected.

43 (d) Examination of Materials. – A wholesale distributor shall visually examine
44 each outside shipping container upon receipt for identity and to prevent the acceptance

1 of contaminated prescription drugs or prescription drugs that are otherwise unfit for
2 distribution. The examination shall be adequate to reveal container damage that would
3 suggest possible contamination or other damage to the contents. A wholesale
4 distributor shall carefully inspect each outgoing shipment for identity of the prescription
5 drugs and to ensure that no prescription drugs that have been damaged in storage or held
6 under improper conditions are delivered.

7 (e) Returned, Damaged, and Outdated Prescription Drugs. – A wholesale
8 distributor shall quarantine and physically separate prescription drugs that are outdated,
9 damaged, deteriorated, misbranded, or adulterated from other prescription drugs until
10 their destruction or their return to their supplier. A prescription drug whose immediate
11 or sealed outer or sealed secondary container has been opened or used shall be identified
12 as having been opened or used and shall be treated in the same manner as outdated
13 prescription drugs.

14 If the conditions under which a prescription drug has been returned to a wholesale
15 distributor cast doubt on the drug's safety, identity, strength, quality, or purity, then the
16 drug shall be destroyed or returned to its supplier unless examination, testing, or other
17 investigation proves that the drug meets appropriate standards of safety, identity,
18 strength, quality, and purity. In determining whether the conditions under which a
19 prescription drug has been returned cast doubt on the drug's safety, identity, strength,
20 quality, or purity, the wholesale distributor shall consider, among other things, the
21 conditions under which the drug has been held, stored, or shipped before or during its
22 return and the condition of the drug and its container, carton, or labeling as a result of
23 storage or shipping.

24 **"§ 106-145.8. Records of prescription drugs.**

25 (a) Records. – A wholesale distributor shall establish and maintain inventories
26 and records of all transactions regarding the receipt and distribution or other disposition
27 of prescription drugs, including all stored prescription drugs, all incoming and outgoing
28 prescription drugs, and all outdated, damaged, deteriorated, misbranded, or adulterated
29 prescription drugs. A wholesale distributor is not required, however, to keep a record of
30 the lot number or expiration date of a prescription drug disposed of or distributed by the
31 distributor.

32 A record of a prescription drug shall include all of the following information:

- 33 (1) The source of the prescription drug, including the name and principal
34 address of the seller or transferor and the address of the location from
35 which the drug was shipped.
- 36 (2) The identity and quantity of the prescription drug received and
37 distributed or disposed of through another method.
- 38 (3) The date the wholesale distributor received the prescription drug and
39 the date the wholesale distributor distributed or otherwise disposed of
40 the drug.
- 41 (4) Documentation of the proper storage of prescription drugs.
42 Documentation may be by manual, electromechanical, or electronic
43 temperature and humidity recording equipment, devices, or logs.

1 A wholesale distributor shall keep a record of a prescription drug for two years after
2 its disposition.

3 (b) Inspection. – A wholesale distributor shall make inventories and records of
4 prescription drugs available for inspection and photocopying by representatives of the
5 Department or authorized federal, State, or local law enforcement officials. A wholesale
6 drug distributor shall permit the Department or an authorized federal, State, or local law
7 enforcement official to enter and inspect the distributor's premises and delivery vehicles
8 and to audit the distributor's records and written operating procedures at reasonable
9 times and in a reasonable manner.

10 A record that is kept at the inspection site or is immediately retrievable by computer
11 or other electronic means shall be readily available for authorized inspection during the
12 two-year retention period. A record kept at a central location apart from the inspection
13 site and not electronically retrievable shall be made available for inspection within two
14 working days of a request by an authorized official of a federal, State, or local law
15 enforcement agency.

16 **"§ 106-145.9. Written procedures concerning prescription drugs and lists of**
17 **responsible persons.**

18 (a) Procedures. – A wholesale distributor shall establish, maintain, and adhere to
19 written procedures for the receipt, security, storage, inventory, and distribution of
20 prescription drugs. These shall include all of the following:

21 (1) A procedure for identifying, recording, and reporting a loss or theft of
22 a prescription drug.

23 (2) A procedure for correcting all errors and inaccuracies in inventories of
24 prescription drugs.

25 (3) A procedure whereby the oldest approved stock of a prescription drug
26 is distributed first. The procedure may permit deviation from this
27 requirement, if the deviation is temporary and appropriate.

28 (4) A procedure for handling recalls and withdrawals of prescription drugs
29 that adequately addresses recalls and withdrawals due to any of the
30 following:

31 a. An action initiated at the request of the Food and Drug
32 Administration or other federal, State, or local law enforcement
33 or other governmental agency, including the Department.

34 b. Any voluntary action by the manufacturer to remove defective
35 or potentially defective prescription drugs from the market.

36 c. Any action undertaken to promote public health and safety by
37 replacing existing prescription drugs with an improved product
38 or new package design.

39 (5) A procedure to ensure that the wholesale distributor prepares for,
40 protects against, and handles any crisis that affects security or
41 operation of any facility in the event of a strike, a fire, flood, or other
42 natural disaster, or another emergency.

1 (6) A procedure to ensure that any outdated prescription drugs are
2 segregated from other prescription drugs and either returned to the
3 manufacturer or destroyed.

4 (b) Responsible Persons. – A wholesale distributor shall establish and maintain
5 lists of officers, directors, managers, and other persons in charge of the distribution,
6 storage, or handling of prescription drugs. The lists shall include a description of the
7 duties of those on the list and a summary of their qualifications.

8 "**§ 106-145.10. Application of other laws.**

9 A wholesale drug distributor shall comply with applicable federal, State, and local
10 laws and regulations. A wholesale distributor that deals in controlled substances shall
11 register with the federal Drug Enforcement Administration (DEA) and shall comply
12 with all applicable federal, State, and local laws and regulations. A wholesale drug
13 distributor is subject to any applicable federal, State, or local laws or regulations that
14 relate to prescription drug salvaging or reprocessing.

15 "**§ 106-145.11. Wholesale Distributor Advisory Committee.**

16 (a) Organization. – The Wholesale Distributor Advisory Committee is created in
17 the Department. The Committee shall consist of five members appointed by the
18 Commissioner as follows:

19 (1) Two members shall be representatives of wholesale distributors.

20 (2) One member shall be a representative of a manufacturer.

21 (3) One member shall be a representative of practicing pharmacists.

22 One member shall be a representative of the consuming public not included in the
23 three categories above.

24 The Committee shall elect a chair and other officers it finds necessary. The
25 Committee shall meet at the call of the chair or upon written notice to all Committee
26 members signed by at least three members. A majority of the Committee is a quorum
27 for the purpose of conducting business. The Department shall provide administrative
28 and clerical support services to the Committee. Members shall be entitled to per diem
29 and reimbursement of expenses as provided in Chapter 138 of the General Statutes.

30 (b) Duties. – The Committee shall do the following:

31 (1) Review all rules to implement this Article that are proposed for
32 adoption by the Commissioner.

33 (2) Advise the Commissioner on the implementation and enforcement of
34 this Article.

35 "**§ 106-145.12. Enforcement and implementation of Article.**

36 The Commissioner shall enforce this Article by using employees of the Department.
37 The Commissioner may enter into agreements with federal, State, or local agencies to
38 facilitate enforcement of this Article. The Commissioner may adopt rules to implement
39 this Article."

40 Sec. 3. G.S. 106-140.1(h) reads as rewritten:

41 "(h) The Commissioner shall ~~issue regulations~~ adopt rules to implement the
42 registration requirements of this section. These ~~regulations~~ rules may provide for an
43 annual registration fee of up to ~~one hundred dollars (\$100.00)~~ five hundred dollars
44 (\$500.00) for companies operating as manufacturers, wholesalers, or repackagers. The

1 Department of Agriculture shall use these funds for the implementation of the North
2 Carolina Food, Drug and Cosmetic Act."

3 Sec. 4. G.S. 106-140.1(f) reads as rewritten:

4 "(f) ~~The foregoing subsections of this section shall not apply.~~ The following classes of
5 people are exempt from the registration requirements of this section:

6 (1) ~~To pharmacists~~ Pharmacists as defined in G.S. 90-85.3(q) holding a
7 valid permit as defined in ~~G.S. 90-85.3(m)~~; G.S. 90-85.3(m).

8 (2) ~~To practitioners~~ Practitioners licensed or registered by law to prescribe
9 or administer drugs and who manufacture, prepare, compound, or
10 process drugs or devices solely for use in the course of their
11 professional ~~practice~~; practice.

12 (3) ~~To persons~~ Persons who manufacture, prepare, compound, or process
13 drugs solely for use in research, teaching, or chemical analysis and not
14 for ~~sale~~; or sale.

15 (4) ~~To such other~~ Other classes of persons as the Commissioner may by
16 ~~regulation~~ rule exempt from the application of this section upon a
17 finding that registration by these classes of persons in accordance with
18 this section is not necessary for the protection of the public health.

19 (5) Wholesale distributors of prescription drugs licensed under G.S. 106-
20 145.3."

21 Sec. 5. This act becomes effective August 1, 1992. Notwithstanding G.S.
22 106-145.4, the Commissioner may issue a wholesale distributor license to an applicant
23 who had a facility in this State on July 1, 1991, without inspecting the facility.