GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1991

H **3**

HOUSE BILL 1010
Committee Substitute Favorable 5/7/91
Committee Substitute #2 Favorable 6/4/91

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 member of a group purchasing organization for the member's own use from the organization, a member of the organization, or a member of a similar organization.

c. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

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

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

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

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

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

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

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

(a) Requirement. – Every wholesale distributor engaged in the wholesale distribution of prescription drugs in interstate commerce in this State shall obtain a license from the Commissioner for each location from which prescription drugs are distributed and shall renew each license annually. A license may cover multiple buildings and multiple operations at a single location, at the wholesale distributor's discretion. A license expires on December 31 of the year in which it is issued. A wholesale distributor licensed under this section is not required to register under G.S. 106-140.1.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The factors to be considered are:

(1) Any convictions of the applicant under any federal, state, or local law relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances.

(2) Any felony convictions of the applicant under federal, state, or local law.

(3) The applicant's past experience in the manufacture or distribution of controlled substances and other prescription drugs.

(4) Whether the applicant has previously given any false or fraudulent information in an application made in connection with prescription drug manufacturing or distribution.

(5) Suspension or revocation by the federal government or a state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any controlled substances or other prescription drugs.

(6) Compliance with the licensing requirements under any previously granted license concerning the manufacture or distribution of prescription drugs.

(7) Compliance with the requirements to maintain or make available to the Commissioner or to a federal, state, or local law enforcement officer those records required under G.S. 106-145.8.

(8) Whether the applicant requires employees of the applicant who are involved in any prescription drug wholesale distribution activity to have education, training, experience, or any combination of these factors sufficient to enable the employee to perform assigned functions in a manner that ensures that prescription drug quality, safety, and security will be maintained at all times as required by law.

(9) Any other factors or qualifications the Commissioner considers relevant to and consistent with the public health and safety.

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

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

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

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

(c) Civil Penalty. – The Commissioner may assess a civil penalty of not more than ten thousand dollars ($10,000) against a person who violates any provision of this Article. In determining the amount of a civil penalty, the Commissioner shall consider the degree and extent of harm caused by the violation. Chapter 150B of the General Statutes governs the assessment of a civil penalty under this subsection. If a civil penalty is not paid within 30 days after the completion of judicial review of a final

agency decision by the Commissioner, the penalty may be collected in any manner by which a debt may be collected. Penalties collected shall be credited to the General Fund.

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

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

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

(3) Have a quarantine area for the storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.

(4) Be maintained in a clean and orderly condition.

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

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

(1) An alarm system to detect entry after hours.

(2) A security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

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

(d) Examination of Materials. – A wholesale distributor shall visually examine each outside shipping container received for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. The examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents. A wholesale distributor shall carefully inspect each outgoing shipment for identity of the prescription drugs and to ensure that no prescription drugs that have been damaged in storage or held under improper conditions are delivered.

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

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

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

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

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

(1) The source of the prescription drug, including the name and principal address of the seller or transferor and the address of the location from which the drug was shipped.

(2) The identity and quantity of the prescription drug received and distributed or disposed of through another method.

(3) The date the wholesale distributor received the prescription drug and the date the wholesale distributor distributed or otherwise disposed of the drug.

(4) Documentation of the proper storage of prescription drugs. Documentation may be by manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs.

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

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

A record that is kept at the inspection site or is immediately retrievable by computer or other electronic means shall be readily available for inspection during the two-year retention period. A record kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by a law enforcement officer.

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

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

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

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

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

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

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

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

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

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

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

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

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

A wholesale drug distributor shall comply with applicable federal, State, and local laws and regulations. A wholesale distributor that deals in controlled substances shall register with the federal Drug Enforcement Administration (DEA) and shall comply with all applicable federal, State, and local laws and regulations. A wholesale drug

distributor is subject to any applicable federal, State, or local laws or regulations that relate to prescription drug salvaging or reprocessing.

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

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

(1) Three members shall be representatives of wholesale distributors.

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

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

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

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

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

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

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

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

Sec. 3. This act becomes effective January 1, 1992. Notwithstanding G.S. 106-145.4, the Commissioner may issue a wholesale distributor license to an applicant who had a facility in this State on July 1, 1991, without inspecting the facility.