GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1991

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HOUSE BILL 1010
Committee Substitute Favorable 5/7/91

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 CFR 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 section to read:

"**§ 106-140.2. Licensing of wholesale prescription drug distributors.**

(a) Purpose and intent. The purpose of this section is to establish a State licensing program for wholesale drug distributors that meets the guidelines established by the federal government in order for these wholesale drug distributors to comply with

federal law. It is the intent of the General Assembly that this section be construed to do only that which is necessary to comply with Public Law 100-293 and 21 CFR Part 205.

(b) Definitions. As used in this section:

(1) 'Blood' means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(2) 'Blood component' means that part of blood separated by physical or mechanical means.

(3) 'Commissioner' means the Commissioner of Agriculture.

(4) 'Department' means the Department of Agriculture.

(5) 'Drug sample' means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(6) 'Manufacturer' means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(7) 'Person' means an individual, corporation, partnership, or any other entity.

(8) 'Prescription drug' means any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(9) 'Wholesale distribution' means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

a. Intracompany sales, defined as any transaction or transfer between any division, subsidiary, parent or affiliated company under common ownership and control of a corporate entity;

b. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

c. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

d. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; 'common control' means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

e. The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this subsection, 'emergency medical reasons'

includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five (5%) percent 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 drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

g. The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

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

(10) 'Wholesale distributor' means anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers, brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

(c) License required; reciprocity; exemption from registration.

(1) Every wholesale distributor who engages in the wholesale distribution of prescription drugs in interstate commerce in this State shall first obtain a license from the Commissioner for each location from which drugs are distributed. A license may include multiple buildings and multiple operations at a single location, at the wholesale distributor's discretion.

(2) The Commissioner may permit out-of-State wholesale drug distributors to become licensed under this section on the basis of reciprocity with other states if (i) the out-of-State wholesale drug distributor possesses a valid license granted by another state pursuant to requirements substantially equivalent to requirements for licensing in this State, and (ii) such other state has agreed to extend reciprocal treatment under its own laws to wholesale drug distributors licensed in this State.

(3) Wholesale drug distributors licensed under this section shall not be required to register pursuant to G.S. 106-140.1.

(d) Application for license; required information.

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

a. The name, full business address, and telephone number of the licensee;

b. All trade or business names used by the licensee;

c. Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;
d. The type of ownership or operation, such as partnership, corporation, or sole proprietorship; and
e. The name(s) of the owner and/or operator of the licensee, including:
1. If an individual, the name of the individual;
2. If a partnership, the name of each partner, and the name of the partnership;
3. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and
4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.
f. Any other information deemed necessary by the Commissioner to determine if the applicant meets the minimum qualifications under subsection (e) of this section.

(2) Initial applications for licenses shall be accompanied by a nonrefundable fee of five hundred dollars ($500.00) for manufacturers or three hundred fifty dollars ($350.00) for others. Applications for renewal of licenses shall be accompanied by a nonrefundable fee of five hundred dollars ($500.00) for manufacturers or three hundred fifty dollars ($350.00) for others. Licenses shall expire annually on December 31.

(3) Changes in any information required by subdivision (1) of this subsection shall be submitted to the Commissioner within 90 days.

(4) A decision shall be made on the license within 90 days after receipt of a completed application.

(e) Minimum qualifications.

(1) The Commissioner shall consider the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the State:
a. Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale, or retail drug distribution, or distribution of controlled substances;
b. Any other felony convictions of the applicant under federal, state, or local laws;
c. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
d. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

e. Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

f. Compliance with licensing requirements under previously granted licenses, if any;

g. Compliance with requirements to maintain and/or make available to the Commissioner or to federal, state, or local law enforcement officials those records required under this subsection; and

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

(2) In the case of a partnership or corporation, these minimum qualifications shall apply to those individuals whose names are included in the license application pursuant to subsection (d) of this section.

(3) The Commissioner shall have the right to deny a license to an applicant if he determines that the granting of such 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.

(f) Personnel. As a condition for receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

(g) Violations; license revocation; penalties.

(1) It shall be unlawful to distribute drugs without the license required herein or to otherwise violate the provisions of this section. Any person found guilty of violating this section shall be imprisoned for not more than 10 years or fined not more than two hundred fifty thousand dollars ($250,000), or both.

(2) The Commissioner may deny, suspend, or revoke the license of any person for any substantial violation or repeated violations of this section, or for conviction of a violation of any other federal, state, or local drug law or regulation.

(3) A civil penalty of not more than ten thousand dollars ($10,000) may be assessed against a person who violates any provision of this section. In determining the amount of the penalty, the Commissioner shall consider the degree and extent of harm caused by the violation. No civil penalty may be assessed unless the person has been given an opportunity for a hearing pursuant to the Administrative Procedure Act. If not paid within 30 days after the exhaustion of administrative

and judicial review of a final decision by the Commissioner, the penalty may be collected in any lawful manner for the collection of a debt. Penalties collected shall be deposited to the General Fund of the State.

(h) Storage and handling; records.

(1) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

a. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

b. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

c. Have a quarantine area for 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;

d. Be maintained in a clean and orderly condition; and

e. Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Security.

a. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

1. Access from outside the premises shall be kept to a minimum and be well-controlled.

2. The outside perimeter of the premises shall be well-lighted.

3. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

b. All facilities shall be equipped with an alarm system to detect entry after hours.

c. All facilities shall be equipped with 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.

(3) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

a. If no storage requirements are established 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.

b. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

c. The record keeping requirements in subdivision (6) of this subsection shall be followed for all stored drugs.

(4) Examination of materials.

a. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

b. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

c. The record keeping requirements in subdivision (6) of this subsection shall be followed for all incoming and outgoing prescription drugs.

(5) Returned, damaged, and outdated prescription drugs.

a. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

b. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

c. If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the 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 drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug 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.

d. The record keeping requirements in subdivision (6) of this subsection shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(6) Record keeping.

a. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other disposition of the drugs.

b. Inventories and records shall be made available for inspection and photocopying by authorized federal, State, or local law enforcement agency officials for a period of two years following disposition of the drugs.

c. Records described in this subsection that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records 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 an authorized official of a federal, State, or local law enforcement agency.

d. Records need not be kept of lot numbers and expiration dates of distributed products.

(7) Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

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

b. A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:
1. Any action initiated at the request of the Food and Drug Administration or other federal, State, or local law enforcement or other government agency, including the State licensing agency;
2. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
3. Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

c. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

d. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.

(8) Responsible persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(9) Compliance with federal, State, and local law. Wholesale drug distributors shall operate in compliance with applicable federal, State, and local laws and regulations.

a. Wholesale drug distributors shall, upon display of appropriate credentials, permit the State licensing authority and authorized federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

b. Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(10) Salvaging and reprocessing. Wholesale drug distributors shall be subject to the provisions of any applicable federal, State, or local laws

or regulations that relate to prescription drug product salvaging or reprocessing.

(i) Advisory committee.

(1) There is created in the Department the Wholesale Drug Distributor Advisory Committee. The Committee shall consist of five members appointed by the Commissioner, as follows:

a. Three members shall be representatives of wholesale drug distributors, as defined in this section;

b. One member shall be a representative of a drug manufacturer; and

c. One member shall be a representative of practicing pharmacists.

(2) The Committee shall elect a chairman and such other officers as it deems necessary. The Committee shall meet when called by the chairman or upon written notice to all Committee members signed by at least three members. A majority of the Committee shall constitute a quorum for the purpose of conducting business. The Department shall provide reasonable 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.

(3) The Committee shall review all rules proposed for adoption hereunder, and shall advise the Commissioner on the implementation and enforcement of this section.

(j) Commissioner; use of fees; agreements; rule-making authority.

(1) This section shall be enforced by the Commissioner, using such employees of the Department as he shall deem necessary. License fees collected by the Department may be used for the administration and enforcement of this section.

(2) Existing facilities operating in this State as of July 1, 1991, may be licensed without an inspection, at the discretion of the Commissioner. New facilities shall be inspected prior to licensure.

(3) The Commissioner may enter into agreements with federal, State, and local agencies to facilitate enforcement of this section.

(4) The Commissioner may adopt such rules as may be necessary to implement this section.

(k) Interpretation of section. This section shall be interpreted to be consistent with Title 21, Code of Federal Regulations, Part 205, Guidelines for State Licensing of Wholesale Prescription Drug Distributors, and in the event of a conflict, the latter shall control.

(l) License fees used to administer and enforce section. All license fees received by the Department under this section shall be deposited in the General Fund, credited to the Department account, and continuously appropriated to the Department for the purpose of administration and enforcement of this section."

Sec. 3. This act becomes effective January 1, 1992.