

CHAPTER 206

AN ACT concerning regulation of pharmaceutical wholesale distributors and amending and supplementing P.L.1961, c.52.

BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

1. Section 1 of P.L.1961, c. 52 (C.24:6B-1) is amended to read as follows:

C.24:6B-1 Registration statement; filing with department.

1. No person shall hereafter engage or continue to engage in a drug manufacturing business or a wholesale non-prescription drug business in this State without first filing a completed registration statement with the department.

2. Section 2 of P.L.1961, c. 52 (C.24:6B-2) is amended to read as follows:

C.24:6B-2 Persons required to sign and verify statement; form and contents.

2. The registration statement shall be signed and verified by the individuals specified in subsection (c) hereof, shall be made on forms prescribed and furnished by the commissioner and shall state such information necessary and proper to the enforcement of this act as the commissioner may require, including:

(a) The name under which the business is conducted.

(b) The address of each location in New Jersey at which the business is to be conducted. If a wholesale non-prescription drug business is not to be conducted from a location within the State, the statement shall give the name and address of an agent resident in this State on whom process against the registrant may be served.

(c) If the registrant is a proprietorship, the name and address of the proprietor; if a partnership, the names and addresses of all partners; if a corporation, the date and place of incorporation, the names and addresses of the president and secretary thereof and the name and address of the designated registered agent in this State; or if any other type of business association, the names and addresses of the principals of such association.

(d) The names and addresses of those individuals having actual administrative responsibility, which in the case of a proprietorship shall be the managing proprietor; partnership, the managing partners; corporation, the officers and directors; or if any other type of association, those having similar administrative responsibilities.

(e) If the business is to be conducted at more than one location in this State, the name and address of the individual in charge of each such location.

(f) A description of the business engaged in and the drug products manufactured for sale or wholesaled.

(g) The name and address of the individual or individuals on whom orders of the commissioner may be served.

(h) A statement as to whether the registrant engages in manufacturing, compounding, processing, wholesaling, jobbing or distribution of depressant or stimulant drugs as defined pursuant to law.

3. Section 12 of P.L.1961, c.52 (C.24:6B-11) is amended to read as follows:

C.24:6B-11 Penalties.

12. (a) Any person who does not comply with an order of the commissioner within the time specified shall be liable for the first offense for a penalty, to be established by the commissioner of not less than \$200 nor more than \$5,000 and for the second and each succeeding offense for a penalty of not less than \$1,000 nor more than \$20,000. The penalties herein provided shall be enforced by the department as plaintiff in a summary proceeding in accordance with the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.).

(b) Any person, who engages or continues to engage in the manufacturing or wholesaling of drugs without having registered with the department as required by this act is guilty of a disorderly persons offense.

4. Section 13 of P.L.1961, c. 52 (C.24:6B-12) is amended to read as follows:

C.24:6B-12 Definitions.

13. For the purposes of this registration act, unless otherwise required by the context:

(a) "Commissioner" means Commissioner of the State Department of Health and Senior Services or his designated representative.

(b) "Department" means the State Department of Health and Senior Services.

(c) "Drugs" means "drugs" and "devices" as defined in R.S. 24:1-1.

(d) "Person" means a natural person, partnership, corporation or any other business association.

(e) "Registrant" means the person in whose name a drug manufacturing business or wholesale non-prescription drug business is registered.

(f) "Drug manufacturing business" means the business of creating, making or producing drugs by compounding, growing or other process. This definition shall apply to persons engaged in the drug manufacturing business who do not maintain a manufacturing location in this State but do operate distribution depots or warehouses of such business in this State. This definition shall not apply to licensed pharmacies or to licensed professional individuals such as, but not limited to, pharmacists, physicians, dentists, or veterinarians when engaged in the lawful pursuit of their professions.

(g) "Wholesale drug business" means the business of supplying non-prescription drugs to persons other than the ultimate consumer. This definition shall not apply to licensed pharmacies or to licensed professional individuals such as, but not limited to, pharmacists, physicians, dentists or veterinarians when engaged in the lawful pursuit of their professions, and shall not apply to a registered drug manufacturing business.

C.24:6B-14 Definitions relative to pharmaceutical wholesale distributors.

5. As used in sections 5 through 24 of P.L.2005, c.206 (C.24:6B-14 et seq.):

"Adulterated" means a prescription drug that is adulterated pursuant to R.S.24:5-10.

"Authenticate" means to affirmatively verify before any distribution of a prescription drug that each transaction listed on the pedigree has occurred.

"Authorized distributor" or "authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's product. An ongoing relationship is deemed to exist when the wholesale distributor, or any member of its affiliated group as defined in section 1504 of the Internal Revenue Code of 1986 (26 U.S.C. s.1504): is listed on the manufacturer's list of authorized distributors; has a written agreement currently in effect with the manufacturer; or has a verifiable account with the manufacturer and meets or exceeds the following transaction or volume requirement thresholds:

a. 5,000 sales units per company within 12 months; or

b. 12 purchases by invoice at the manufacturer's minimum purchasing requirement per invoice within 12 months.

"Centralized prescription processing" means the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing, drug utilization review, claims adjudication, refill authorizations and therapeutic interventions.

"Chain pharmacy distribution center" means a distribution facility or warehouse owned by and operated for the primary use of a group of pharmacies that are under common or affiliated control or ownership.

"Commissioner" means the Commissioner of Health and Senior Services.

"Contraband" with respect to a prescription drug means: counterfeit; stolen; misbranded; obtained by fraud; purchased by a nonprofit institution for its own use and placed in commerce in violation of the own use agreement; or the existing documentation or pedigree, if required, for the prescription drug has been forged, counterfeited, falsely created, or contains any altered, false or misrepresented information.

"Counterfeit prescription drug" means a prescription drug, or the container, shipping container, seal or labeling thereof, which, without authorization, bears the trademark, trade name

or other identifying mark, imprint, or any likeness thereof, of a manufacturer, processor, packer or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such prescription drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other manufacturer, processor, packer or distributor.

"DEA" means the federal Drug Enforcement Administration.

"Department" means the Department of Health and Senior Services.

"Designated representative" means an individual who is designated by a wholesale prescription drug distributor to serve as the primary contact person for the wholesale distributor with the department, and who is responsible for managing the company's operations at that licensed location.

"Distribute" means to sell, offer to sell, deliver, offer to deliver, broker, give away or transfer a prescription drug, whether by passage of title, physical movement, or both. The term does not mean to: dispense or administer; deliver or offer to deliver in the usual course of business as a common carrier or logistics provider; or provide a sample to a patient by a licensed practitioner, a health care professional acting at the direction and under the supervision of a practitioner, or the pharmacist of a health care facility licensed pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) acting at the direction of a practitioner.

"Drug" means: a. an article or substance recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them; b. an article or substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; c. an article or substance, other than food, intended to affect the structure of any function of the body of man or animals; and d. an article or substance intended for use as a component of any article or substance specified in clause a., b. or c.; but does not include devices or their components, parts or accessories. Drug includes a prefilled syringe or needle.

"Immediate container" means a container but does not include package liners.

"Logistics provider" means an entity that receives drugs from the original manufacturer and delivers them at the direction of that manufacturer, and does not purchase, sell, trade or take title to the drugs.

"Misbranded" means a prescription drug with respect to which the label is: false or misleading in any particular; does not bear the name and address of the manufacturer, packer or distributor and does not have an accurate statement of the quantities of the active ingredients; or does not show an accurate monograph for legend drugs; or is misbranded based upon other considerations as provided in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s.301 et seq.

"Pedigree" means a statement or record identifying each previous sale of a prescription drug, from the sale by a manufacturer through acquisition and sale by a wholesale distributor, including each distribution to an authorized distributor, starting with the last authorized distributor, or the manufacturer if the prescription drug has not been purchased previously by an authorized distributor or is a prescription drug on the specified list of susceptible products. A pedigree shall include the following information: the proprietary and established name of the prescription drug; the dosage; container size; number of containers; the date, business name and address of all parties to each prior transaction involving the prescription drug starting with the last authorized distributor or the manufacturer if the prescription drug has not been purchased previously by an authorized distributor or is a prescription drug on the specified list of susceptible products.

"Repackage" means changing the container, wrapper, quantity or labeling of a prescription drug to further its distribution.

"Sales unit" means the unit of measure that the manufacturer uses to invoice its customer for the particular product.

"Specified list of susceptible products" means a specific list of prescription drugs, to be determined by the commissioner, that are considered to be potential targets for adulteration, counterfeiting or diversion, which the commissioner shall provide to wholesale distributors as prescription drugs are added to or removed from the list, along with notification of those changes.

"Wholesale distribution" means the distribution of prescription drugs in or into the State by

a wholesale distributor to a person other than a consumer or patient, and includes transfers of prescription drugs from one pharmacy to another pharmacy if the value of the goods transferred exceeds 5% of total prescription drug sales revenue of either the transferor or transferee pharmacy during any consecutive 12-month period. The term excludes:

a. 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;

b. the sale, purchase or trade of a prescription drug, or an offer to sell, purchase or trade a prescription drug for emergency medical reasons;

c. the sale, purchase or trade of a prescription drug, or an offer to sell, purchase or trade a prescription drug by pharmacies, chain pharmacy distribution centers, and the associated transfer of goods between chain pharmacy distribution centers and their servicing wholesale distributors or manufacturers;

d. intracompany transactions or sales among wholesale distributors, chain pharmacy distribution centers, and pharmacies, and which are limited to those sales or transfers of a prescription drug among members of an affiliated group, even if the members of the affiliated group are separate legal entities;

e. 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 licensed pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) that are under common control;

f. the sale, purchase or trade of a prescription drug, or offer to sell, purchase or trade a prescription drug by a charitable organization exempt from taxation pursuant to section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. s.501(c)(3)) to a nonprofit affiliate of the organization;

g. the purchase or other acquisition by a hospital or other similar health care entity licensed pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;

h. the transfer of prescription drugs between pharmacies pursuant to a centralized prescription processing agreement;

i. the distribution of prescription drug samples by manufacturers' representatives or wholesale distributors' representatives;

j. the sale, purchase or trade of blood and blood components intended for transfusion;

k. prescription drug returns, when conducted by a pharmacy, chain pharmacy distribution center, hospital, health care entity licensed pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) or charitable institution in accordance with regulations established by the commissioner;

l. the sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use;

m. the stockpiling and distribution of drugs under the authorization of a State agency for the purpose of providing those products in an emergency situation; or

n. the sale, transfer, merger or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies whether accomplished as a purchase and sale of stock or business assets.

"Wholesale distributor" means any person, other than the manufacturer, pharmacy, logistics provider, chain pharmacy distribution center, engaged in wholesale distribution of prescription drugs in or into the State and includes repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses including distributors' warehouses, independent prescription drug traders, and retail pharmacies that conduct wholesale distribution.

C.24:6B-15 Licensure required for pharmaceutical wholesale distributors.

6. a. A wholesale distributor engaged in the wholesale distribution of prescription drugs within this State, whether or not the wholesale distributor is located in this State, shall be licensed by the department. If wholesale distribution operations are conducted at more than one location, each such location shall be licensed. The department may establish reciprocal agreements with any state that has a drug wholesale licensure and standards program that is at

least as protective as the requirements set forth under this act.

b. A wholesale distributor shall renew its license annually and pay a license fee established by the commissioner. License fees shall be used to support administrative and programmatic activities under this act.

c. The commissioner shall establish the licensing and renewal form and application process. An applicant shall provide the following information, in addition to any other information that the commissioner may require:

(1) all trade or business names, including current and former fictitious business names used by the licensee, which names shall not be identical to any name used by another unrelated wholesale distributor licensed to purchase or sell prescription drugs in this State;

(2) the name, business address, Social Security number and date of birth of each owner, partner or sole proprietor, as applicable, and each operator, and

(a) if a partnership, the business name of the partnership and federal employer identification number;

(b) if a corporation, the name, business address, Social Security number, date of birth, and title of each corporate officer and director, the corporate name including the name of any parent company, the state of incorporation, federal employer identification number and name, address and Social Security number of each shareholder owning 10% or more of voting stock;

(c) if a sole proprietorship, the federal employer identification number; or

(d) if a limited liability company, the name of each member and each manager, the company name and federal employer identification number;

(3) the name, business address and telephone number of each person who is serving as the designated representative pursuant to section 10 of this act;

(4) a list of states in which the wholesale distributor is licensed to purchase, possess and distribute prescription drugs, and into which it ships prescription drugs;

(5) information regarding general and product liability insurance, including certification of relevant coverage;

(6) a list of managerial employees;

(7) a list of all disciplinary actions by state and federal agencies over the last four years;

(8) a description, including the address, dimensions, and other relevant information, of each facility or warehouse used for prescription drug storage and distribution;

(9) a description of prescription drug import and export activities of the wholesale distributor;

(10) a description of the applicant's written procedures as required under section 19 of this act; and

(11) if involved in the distribution of controlled dangerous substances, evidence of registration with the department, as required in section 2 of P.L.1970, c.226 (C.24:21-10), and evidence of registration with the DEA.

d. (1) The commissioner shall require from an applicant a surety bond of not less than \$100,000, or evidence of other equivalent means of security acceptable to the department, such as insurance, an irrevocable letter of credit or funds deposited in a trust account or financial institution to secure payment of any administrative penalties imposed by the department and any fees or costs incurred by the department regarding that license when those penalties, fees or costs are authorized under State law and the licensee fails to pay 30 days after the penalty, fees or costs becomes final.

(2) The commissioner may accept a surety bond of \$25,000 if the annual gross receipts of the previous tax year for the wholesale distributor is \$10,000,000 or less.

(3) A separate surety bond or other equivalent means of security shall not be required for each company's separate locations or for affiliated companies or groups when those separate locations or affiliated companies or groups are required to apply for or renew their wholesale distributor license with the department.

(4) The surety bond requirement may be waived, at the discretion of the commissioner, if the wholesale distributor previously has obtained a comparable surety bond or

other equivalent means of security for the purpose of licensure in another state where the wholesale distributor possesses a valid license in good standing, provided that a reciprocal agreement exists between this State and the other state that extends authority to this State to make a claim against the surety bond or other equivalent means of security.

(5) The department may make a claim against the bond or other equivalent means of security until one year after the wholesale distributor's license ceases to be valid or until 60 days after the conclusion of any administrative or legal proceeding before or on behalf of the department which involves the wholesale distributor, including any appeal, whichever occurs later.

e. A licensed wholesale distributor located outside this State who distributes prescription drugs in this State may designate a registered agent in this State for service of process. A licensed wholesale distributor who fails to designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful attorney.

f. Each wholesale distribution facility in this State shall undergo an inspection by the department prior to initial licensure and at least once every three years thereafter, in accordance with a schedule to be determined by the commissioner. The department shall use qualified inspectors specifically trained to conduct inspections of wholesale distributors, who shall be required to maintain current training and knowledge regarding the wholesale prescription drug distribution industry. The department may contract with a third party organization that is nationally recognized as having expertise in pharmaceutical drug distribution to meet the inspection requirements of this section.

g. A wholesale distributor shall publicly display or have readily available all licenses and the most recent inspection report issued by the department.

h. The department shall make publicly available on its website the dates of the first and most recent inspections of each wholesale distributor.

i. The department shall notify appropriate parties upon the suspension, revocation or expiration, or other relevant action regarding, a wholesale distributor's license and make that information available on its website within five business days.

j. A licensee shall submit to the department any change in information within 30 days of that change, unless otherwise noted.

C.24:6B-16 Criminal history record background check for applicants, designated representatives, person enumerated.

7. a. The commissioner shall require each applicant, designated representative or any person enumerated in subsection c. of section 6 of this act, in accordance with applicable State and federal laws, rules and regulations, to undergo a criminal history record background check.

The commissioner is authorized to exchange fingerprint data with and receive criminal history record background information from the Division of State Police and the Federal Bureau of Investigation consistent with the provisions of applicable federal and State laws, rules and regulations. The Division of State Police shall forward criminal history record background information to the commissioner in a timely manner when requested pursuant to the provisions of this section.

An applicant, designated representative or any person enumerated in subsection c. of section 6 of this act shall submit to being fingerprinted in accordance with applicable State and federal laws, rules and regulations. No check of criminal history record background information shall be performed pursuant to this section unless the applicant, designated representative or person enumerated in subsection c. of section 6 of this act has furnished his or her written consent to that check. An applicant, designated representative or person enumerated in subsection c. of section 6 of this act who refuses to consent to, or cooperate in, the securing of a check of criminal history record background information shall not be considered for licensure. An applicant, designated representative or person enumerated in subsection c. of section 6 of this act shall bear the cost for the criminal history record background check, including all costs of administering and processing the check.

b. The commissioner shall not license an applicant, designated representative or any person

enumerated in subsection c. of section 6 of this act if the criminal history record background information reveals a disqualifying conviction. For the purposes of this section, a disqualifying conviction shall mean a conviction of any of the following crimes and offenses:

(1) In New Jersey, any crime or disorderly persons offense:

(a) involving danger to the person, meaning those crimes and disorderly persons offenses set forth in N.J.S.2C:11-1 et seq., N.J.S.2C:12-1 et seq., N.J.S.2C:13-1 et seq., N.J.S.2C:14-1 et seq. or N.J.S.2C:15-1 et seq.; or

(b) involving theft as set forth in chapter 20 of Title 2C of the New Jersey Statutes; or

(c) involving health care claims fraud as set forth in P.L.1997, c.353 (C.2C:21-4.2 et al.) or insurance fraud as set forth in sections 72 and 73 of P.L.2003, c.89 (C.2C:21-4.5 and 2C:21-4.6); or

(d) involving any controlled dangerous substance or controlled substance analog as set forth in chapter 35 of Title 2C of the New Jersey Statutes except paragraph (4) of subsection a. of N.J.S.2C:35-10; or

(2) In any other state or jurisdiction, of conduct which, if committed in New Jersey, would constitute any of the crimes or disorderly persons offenses described in paragraph (1) of this subsection; or

(3) Any violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s.301 et seq.

c. Upon receipt of the criminal history record background information from the Division of State Police and the Federal Bureau of Investigation, the commissioner shall provide written notification to the applicant, designated representative or person enumerated in subsection c. of section 6 of this act, of his or her qualification for or disqualification from licensure.

If the applicant, designated representative or person enumerated in subsection c. of section 6 of this act is disqualified because of a disqualifying conviction pursuant to the provisions of this section, the conviction that constitutes the basis for the disqualification shall be identified in the written notice.

d. The Division of State Police shall promptly notify the commissioner in the event that an individual who was the subject of a criminal history record background check conducted pursuant to this section is convicted of a crime or offense in this State after the date the background check was performed. Upon receipt of that notification, the commissioner shall make a determination regarding the continued eligibility for licensure of the applicant, designated representative or person enumerated in subsection c. of section 6 of this act.

e. Notwithstanding the provisions of subsection b. of this section to the contrary, the commissioner may offer provisional licensure for a period not to exceed three months if the applicant, designated representative or person enumerated in subsection c. of section 6 of this act submits to the commissioner a sworn statement attesting that the person has not been convicted of any disqualifying conviction pursuant to this section, and the commissioner determines that no criminal history record background information exists on file in the Division of State Police or the Federal Bureau of Investigation which would disqualify the person.

f. Notwithstanding the provisions of subsection b. of this section to the contrary, no applicant, designated representative or person enumerated in subsection c. of section 6 of this act shall be disqualified from licensure on the basis of any conviction disclosed by a criminal history record background check conducted pursuant to this section if the applicant, designated representative or person enumerated in subsection c. of section 6 of this act has affirmatively demonstrated to the commissioner clear and convincing evidence of rehabilitation. In determining whether clear and convincing evidence of rehabilitation has been demonstrated, the following factors shall be considered:

(1) the nature and responsibility of the position which the convicted individual would hold, has held or currently holds;

(2) the nature and seriousness of the crime or offense;

(3) the circumstances under which the crime or offense occurred;

(4) the date of the crime or offense;

(5) the age of the individual when the crime or offense was committed;

- (6) whether the crime or offense was an isolated or repeated incident;
- (7) any social conditions which may have contributed to the commission of the crime or offense; and
- (8) any evidence of rehabilitation, including good conduct in prison or in the community, counseling or psychiatric treatment received, acquisition of additional academic or vocational schooling, successful participation in correctional work-release programs, or the recommendation of those who have had the individual under their supervision.

C.24:6B-17 Establishment, maintenance of list of authorized distributors.

8. a. A manufacturer that is registered with the department pursuant to P.L.1961, c.52 (C.24:6B-1 et seq.) shall establish and maintain an up-to-date list of its authorized distributors and authorized distributors of record, as defined in section 5 of this act. The list shall be filed with the department, and each manufacturer shall publish the list on its website. The department shall provide electronic links to each manufacturer's website from the department's website. A manufacturer shall notify the department within 10 business days of any change to the list.

b. The commissioner may determine that a wholesale distributor is an authorized distributor if the wholesale distributor can demonstrate that it has a written agreement currently in effect with a manufacturer or a verifiable account with a manufacturer and meets the following transaction or volume requirement thresholds:

- (1) 5,000 sales units per company within 12 months; or
- (2) 12 purchases by invoice at the manufacturer's minimum purchasing requirement per invoice within 12 months.

C.24:6B-18 Determination of eligibility for licensure renewal.

9. The department shall determine eligibility for licensure and renewal thereof, of persons engaged in the wholesale distribution of prescription drugs. In addition to any additional factors that the commissioner may deem relevant to protecting the public health and safety, the following shall be considered in determining an applicant's eligibility:

- a. any suspension, sanction or revocation by a federal, state or local government of any license currently or previously held by the applicant or any of its owners for violations of laws regarding drugs;
- b. the results of the applicant's criminal history record background check pursuant to section 7 of this act and information regarding the applicant's business provided pursuant to section 6 of this act;
- c. the applicant's past experience in the manufacturing or distribution of drugs;
- d. whether the applicant furnished false or fraudulent material in any application related to drug manufacturing or distribution;
- e. compliance with previously granted licenses related to drug distribution or any health care professional or occupational licenses; and
- f. a driver's license and Social Security number verification for all company officers, key management, principals and owners, provided that the review does not conflict with State confidentiality laws.

C.24:6B-19 Additional requirements for designated representative.

10. In addition to satisfying any requirements that the commissioner may establish by regulation, a designated representative shall:

- a. submit an application that includes the following information:
 - (1) the person's date and place of birth;
 - (2) the person's occupations, positions of employment and offices held during the past seven years, and the principal business addresses;
 - (3) whether the person has been temporarily or permanently enjoined by a court of competent jurisdiction during the past four years for violating any federal or state law regulating drugs, along with the details of those events;
 - (4) a description of any involvement by the person with any business that

manufactured, administered, prescribed, distributed or stored prescription drugs and was named as a party in a lawsuit;

(5) a photograph of the person taken within the previous 30 days;

(6) the name, business address, occupation, date and place of birth for each member of the person's immediate family who is employed by the wholesale distributor in a management or operations position or has ownership in the wholesale distribution business. As used in this paragraph, the term "member of the person's immediate family" includes the person's spouse, children, parents and siblings, and the spouses of the person's children and the person's siblings; and

(7) such other information as the commissioner deems relevant.

b. have a minimum of two years of verifiable, full-time managerial, supervisory, auditing or compliance experience with: (1) a pharmacy, wholesale distributor or drug manufacturer licensed, permitted or registered in this or another state, territory of the United States or the District of Columbia; (2) a nationally recognized drug trade association; or (3) a state or federal agency, where the person's responsibilities included record keeping, storage and shipment of prescription drugs;

c. serve as the designated representative for only one wholesale distributor location at any one time; and

d. be actively involved in and aware of the actual daily operations of the wholesale distributor. As used in this subsection, "actively involved" means being: employed full-time in a managerial position; physically present at the facility during normal business hours; and knowledgeable about all policies and procedures pertaining to the wholesale distributor's operations. A designated representative may seek assistance from qualified individuals to help ensure compliance with the provisions of this subsection.

C.24:6B-20 Requirements for facilities used for wholesale prescription drug distribution.

11. All facilities used for wholesale prescription drug distribution shall:

a. be of suitable construction to ensure that all prescription drugs in the facilities are maintained in accordance with their labeling or official compendium standards;

b. be of suitable size and construction to facilitate cleaning, maintenance and proper wholesale distribution operations;

c. have adequate storage, lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

d. have a quarantine area for prescription drugs that are adulterated, counterfeit or suspected of being counterfeit, or otherwise unfit for distribution;

e. be maintained in a clean and orderly condition and free from infestation;

f. be secure from unauthorized entry, with the outside perimeter of the premises well-lighted and entry into areas where prescription drugs are held limited to authorized personnel;

g. be equipped with security and inventory management and control systems that provide suitable protection against theft, diversion or counterfeiting, and can readily provide data to the department; and

h. be a commercial location and not a personal dwelling or residence.

C.24:6B-21 Provision of pedigree, certification prior to sale, return of prescription drug.

12. a. Before the sale or return of a prescription drug to another wholesale distributor, a selling wholesale distributor shall provide a pedigree or a certification in accordance with the following specifications:

(1) if the seller is an authorized distributor of record, a pedigree for each prescription drug that is included on the specified list of susceptible products and was not purchased directly from the manufacturer; or

(2) if the seller is neither the prescription drug manufacturer nor an authorized distributor of record, a pedigree for each prescription drug that is distributed.

b. A wholesale distributor shall provide for the secure and confidential storage of

information with restricted access and policies and procedures to protect the integrity and confidentiality of the information.

c. A wholesale distributor shall conduct business in a commercial location, and not a personal dwelling or residence.

d. A wholesale distributor shall provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting or diversion of prescription drugs.

C.24:6B-22 Annual report to the Legislature on tracking system.

13. The commissioner shall report annually to the Legislature on the availability of an effective standardized electronic product identification tracking system for prescription drugs in this State. The report shall address whether such a system can be feasibly implemented by manufacturers, wholesale distributors and pharmacies for purposes of authentication, and deterrence and detection of counterfeit drugs. If the commissioner determines that implementation of such a system is feasible, he shall make recommendations regarding the timing and method of implementing the system.

C.24:6B-23 Authentication of distribution of prescription drug.

14. a. (1) A wholesale distributor shall authenticate every distribution of a prescription drug back to the manufacturer if the wholesale distributor has reason to believe that a prescription drug purchased from another wholesale distributor is adulterated, misbranded or counterfeit.

(2) A wholesale distributor who distributed a prescription drug that is the subject of an authentication pursuant to this section shall provide, upon request, information regarding the distribution of the prescription drug, including: date of purchase; sales invoice number; and contact information for the wholesale distributor who sold the prescription drug, including the name, address, telephone number and e-mail address, if available.

(3) If a wholesale distributor is unable to authenticate each transfer, the wholesale distributor shall quarantine the prescription drug and report this to the department within 14 days after completing the attempted authentication.

(4) If the wholesale distributor satisfactorily completes the authentication, the wholesale distributor shall maintain records of the authentication for two years, and produce them to the department and the Department of Law and Public Safety, upon request.

b. (1) A wholesale distributor shall conduct annual random authentications on at least 10% of pedigrees as required by this act.

(2) A wholesale distributor shall conduct annual random authentications on at least 90% of the pedigrees of prescription drugs designated on the specified list of susceptible products for which a pedigree is required.

(3) A wholesale distributor and a manufacturer from whom other wholesale distributors have purchased prescription drugs shall cooperate with random authentications of pedigrees and provide requested information in a timely manner.

C.24:6B-24 Examination of shipping container.

15. a. A wholesale distributor shall visually examine each shipping container upon receipt to ensure its identity and to determine if it contains prescription drugs that are adulterated, contraband, counterfeit, suspected of being contraband or counterfeit, or otherwise unfit.

b. Containers found to be unacceptable under subsection a. of this section shall be quarantined from the rest of stock until an examination and determination are made that the contents are not adulterated, contraband, counterfeit, or otherwise unfit.

c. Upon receipt of a shipping container, a wholesale distributor shall review its records for the acquisition of prescription drugs for accuracy and completeness.

d. Each outgoing shipment shall be carefully inspected for identity and to ensure that it has been stored under proper conditions.

e. Disposal and destruction of containers, labels and packing shall be conducted in a manner to ensure that they cannot be used in counterfeiting activities. Appropriate witnessing of the destruction and disposal shall be in accordance with federal and State requirements.

C.24:6B-25 Criteria for return of prescription drug to wholesale distributor.

16. a. (1) A pharmacy, chain pharmacy distribution center or pharmacy member of an affiliated group shall return to a wholesale distributor any prescription drug that is on the specified list of susceptible products if the prescription drug:

(a) was ordered by a pharmacy or delivered to a pharmacy by a wholesale distributor in error or in excess of need;

(b) is identified by the pharmacy as such within 30 business days of receipt or pursuant to the retail agreement in place between the pharmacy and wholesale distributor;

(c) has been maintained in its original packaging;

(d) has had its integrity maintained; and

(e) is accompanied by appropriate and complete documentation and, where applicable, any necessary notations made to the certification, invoice or packing slip.

(2) The prescription drug shall be physically returned within 30 business days of notification to the wholesale distributor or as consistent with the wholesale distributor's return policy. If the prescription drug cannot be returned to the wholesale distributor, it shall be returned to the manufacturer.

b. A prescription drug manufacturer shall accept return of prescription drugs on the specified list of susceptible products that have not been returned to a wholesale distributor in accordance with the time frame specified in paragraph (2) of subsection a. of this section.

c. A wholesale distributor shall quarantine a prescription drug, container or labeling that is received outdated, damaged, deteriorated, misbranded, counterfeited, suspected of being counterfeited, adulterated, or otherwise deemed unfit for human consumption until it is returned.

d. A manufacturer or wholesale distributor who receives returned prescription drugs shall notify the department of the return.

e. A wholesale distributor shall identify a prescription drug that becomes outdated after receipt and has been opened or used, but is not adulterated, misbranded, counterfeited, or suspected of being counterfeit, and quarantine the drug until it is destroyed or returned.

f. A prescription drug that becomes outdated after receipt and has been unopened or unused, but is not adulterated, misbranded, counterfeit or suspected of being counterfeit shall be so identified and quarantined until it is destroyed or returned.

g. A wholesale distributor shall return or destroy, within 30 business days after discovery, a prescription drug that has been returned, if any condition under which it has been returned casts doubt on its safety, identity, strength, quality or purity.

h. A wholesale distributor:

(1) shall retain discovered contraband, counterfeit, or suspected counterfeit prescription drugs, evidence of criminal activity and accompanying documentation until its disposition is authorized by the department; and

(2) shall not destroy the shipping container, immediate or sealed outer or secondary container or labeling, and accompanying documentation, which is suspected of or determined to be counterfeit or fraudulent, until its disposition is authorized by the department.

C.24:6B-26 Requirements for wholesale distributor.

17. A wholesale distributor shall exercise due diligence in accordance with the following requirements, unless the commissioner waives any requirement. Prior to the first purchase of prescription drugs for distribution in this State from another wholesale distributor that is not licensed in this State pursuant to this act, the purchasing wholesale distributor shall obtain the following information from the selling wholesale distributor:

a. verification of the wholesale distributor's status as an authorized distributor of record, if applicable, for which purpose inclusion of the wholesale distributor's business name on the manufacturer's list of authorized distributors of record, as required in section 8 of this act, shall be deemed acceptable for verification purposes;

b. a list of the state in which the wholesale distributor is domiciled and the states into which it ships prescription drugs;

- c. the wholesale distributor's most recent facility inspection reports;
- d. copies of relevant general and product liability insurance coverage;
- e. a list of any other names under which the wholesale distributor does business or was formerly known;
- f. names of corporate officers and managerial employees;
- g. a list of all disciplinary actions by state and federal agencies involving wholesale distribution of drugs for the last four years, if the selling wholesale distributor supplies it upon request by the purchasing wholesale distributor; and
- h. a description, including the address, dimensions and other relevant information, of each facility used for prescription drug storage and distribution.

C.24:6B-27 Maintenance of document, record relative to pedigree, certification.

18. a. A person who receives or passes a pedigree or certification pursuant to this act shall maintain the document or record for three years from receipt or passing of the document or record.

b. A wholesale distributor shall:

- (1) establish and maintain records of all transactions regarding the receipt, distribution or other disposition of all prescription drugs, including the dates of receipt and distribution or other disposition of the prescription drugs; and
- (2) make its inventories and other records available for inspection and copying by an authorized official of any local, State or federal governmental agency for a period of three years following the creation of those records.

c. A wholesale distributor shall ensure that its records as described in this section:

- (1) if kept at the inspection site or immediately retrievable by computer or other electronic means, are readily available for authorized inspection during the retention period; and
- (2) if kept at a central location apart from the inspection site and not electronically retrievable, are made available for inspection within two business days of a request by an authorized official of any State or federal governmental agency charged with enforcement of the provisions of this act.

d. A wholesale distributor shall maintain an ongoing list of persons with whom it does business related to prescription drugs.

e. A wholesale distributor shall establish and maintain procedures for reporting counterfeit or suspected counterfeit prescription drugs, or counterfeiting or suspected counterfeiting activities to the department.

f. A wholesale distributor shall maintain a system for mandatory reporting to the department of significant shortages or losses of prescription drugs when diversion of prescription drugs is known or suspected.

C.24:6B-28 Adherence to written policies, procedures by wholesale distributors.

19. a. A wholesale distributor shall establish, maintain and adhere to written policies and procedures for the receipt, security, storage, inventory, transport, shipping and distribution of prescription drugs, including policies and procedures for: identifying, recording and reporting losses or thefts; correcting all errors and inaccuracies in inventories; and implementing and maintaining a continuous quality improvement system.

b. Pursuant to subsection a. of this section, a wholesale distributor shall establish procedures:

- (1) for handling recalls and withdrawals of prescription drugs;
- (2) to prepare for and protect against any crisis that affects the security or operation of any facility;
- (3) for segregating, returning and destroying prescription drugs, and providing all necessary documentation;
- (4) for disposal and destruction of containers, labels and packaging to ensure that they cannot be used in counterfeiting activities, which procedures shall require retention of all necessary documentation for at least three years, and appropriate witnessing of the destruction of any labels, packaging, immediate containers or containers in accordance with federal and State

requirements;

(5) for investigating and reporting significant inventory discrepancies to the department;

(6) for reporting criminal or suspected criminal activities involving the inventory of prescription drugs to the department within five business days of discovery and for reporting suspected criminal activities involving prescription drugs that are also controlled substances to the department; and

(7) for satisfying authentication requirements required by section 14 of this act.

C.24:6B-29 Violations, graduation of offenses.

20. a. A person is guilty of a crime of the third degree if the person:

(1) engages in the wholesale distribution of prescription drugs and, with intent to defraud or deceive, fails to deliver to another person a complete and accurate pedigree, when required, prior to transferring the prescription drug to another person;

(2) engages in the wholesale distribution of prescription drugs and, with intent to defraud or deceive, fails to acquire a complete and accurate pedigree, when required, concerning a prescription drug prior to obtaining the prescription drug from another person;

(3) engages in the wholesale distribution of prescription drugs, and knowingly destroys, alters, conceals or fails to maintain a complete and accurate pedigree concerning any prescription drug in the person's possession;

(4) engages in the wholesale distribution of prescription drugs and possesses pedigree documents required by the department, and knowingly fails to authenticate the matters contained in the documents as required, but nevertheless distributes or attempts to further distribute prescription drugs;

(5) engages in the wholesale distribution of prescription drugs and, with intent to defraud or deceive, falsely swears or certifies that the person has authenticated any documents related to the wholesale distribution of prescription drugs;

(6) engages in the wholesale distribution of prescription drugs and knowingly forges, counterfeits or falsely creates any pedigree, and falsely represents any factual matter contained on any pedigree or knowingly omits to record material information required to be recorded in a pedigree;

(7) engages in the wholesale distribution of prescription drugs and knowingly purchases or receives prescription drugs from a person not authorized to distribute prescription drugs in wholesale distribution;

(8) engages in the wholesale distribution of prescription drugs and knowingly sells, barter, brokers or transfers prescription drugs to a person not authorized to purchase prescription drugs, under the jurisdiction in which the person receives the prescription drugs in a wholesale distribution;

(9) knowingly possesses, actually or constructively, any amount of a contraband prescription drug and knowingly sells or delivers, or possesses with intent to sell or deliver, any amount of the contraband prescription drug;

(10) knowingly forges, counterfeits or falsely creates any label for a prescription drug or falsely represents any factual matter contained in any label of a prescription drug; or

(11) knowingly manufactures, purchases, sells, delivers or brings into the State, or is knowingly in actual or constructive possession of any amount of a contraband prescription drug.

b. A person who knowingly manufactures, purchases, sells, delivers or brings into the State, or is knowingly in actual or constructive possession of, any amount of a contraband prescription drug, and whose actions as described in this subsection result in the death of a person, is guilty of a crime of the first degree.

c. A person who engages in the wholesale distribution of prescription drugs without having registered with the department as required pursuant to this act is guilty of a disorderly persons offense.

C.24:6B-30 Noncompliance with orders, penalties.

21. a. Any person who does not comply with an order of the commissioner within the time specified shall be liable to a penalty, to be established by the commissioner as follows: for the first offense, not less than \$200 nor more than \$5,000; and, for the second and each succeeding offense, not less than \$1,000 nor more than \$20,000. The penalties shall be enforced by the department as plaintiff in a summary proceeding in accordance with the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.).

b. Nothing in this act shall be construed to prevent or limit the commissioner, the Division of Consumer Affairs in the Department of Law and Public Safety or any appropriate board under the purview of the Division of Consumer Affairs, or the Attorney General from taking any other action permitted by law against a person who violates the provisions of this act.

C.24:6B-31 Real, personal property, certain, subject to forfeiture.

22. Any real or personal property which was used or intended to be used to commit, facilitate or promote the commission of the crime, or which constitutes, is derived from, or is traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the crime, shall be subject to forfeiture in accordance with the provisions of N.J.S. 2C:64-1 et seq.

C.24:6B-32 Wholesale Drug Distribution Advisory Council.

23. a. There is created a Wholesale Drug Distribution Advisory Council within the department to advise the department regarding proposed rules on the distribution of prescription drugs and to recommend any practical measures that may improve the integrity of the prescription drug distribution system.

b. The council shall be comprised of eight members as follows:

(1) the commissioner and the Director of the Division of Consumer Affairs in the Department of Law and Public Safety, or their designees, who shall serve ex officio;

(2) three persons employed by different wholesale distributors licensed in this State, one of whom shall be appointed by the Governor, one by the President of the Senate and one by the Speaker of the General Assembly;

(3) one person employed by a prescription drug manufacturer, appointed by the Governor;

(4) one pharmacist, appointed by the Speaker of the General Assembly; and

(5) one representative of a chain pharmacy distribution center, appointed by the President of the Senate.

c. The public members shall serve for a term of three years; but, of the members first appointed, two shall serve for a term of one year, two for a term of two years, and two for a term of three years. Members are eligible for reappointment upon the expiration of their terms. Vacancies in the membership of the council shall be filled in the same manner provided for the original appointments.

d. The public members shall be appointed, and the council shall organize as soon as practicable following their appointment, but no later than 60 days after the date of enactment of this act. The members shall select a chairperson and vice-chairperson from among the membership of the council. The chairperson shall appoint a secretary, who need not be a member of the council.

e. The members shall serve without compensation, but shall be reimbursed for necessary expenses incurred in performing their duties and within the limits of available funds.

C.24:6B-33 Rules, regulations.

24. In accordance with the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), the commissioner shall adopt rules and regulations to ensure the safety and sanitary conduct of pharmaceutical distribution and to carry out the provisions of this act.

25. This act shall take effect on the 180th day after enactment, except that the Commissioner of Health and Senior Services may take such anticipatory administrative action in advance as

shall be necessary for the implementation of the act.

Approved August 24, 2005.