NEW JERSEY REGISTRATION
OF WHOLESALE DISTRIBUTORS OF DRUGS
NJAC 8:21-3A

§ 8:21-3A.1 Scope

This subchapter sets forth standards for the registration and operation of any person, partnership, corporation or business firm engaging in the wholesale distribution of drugs.

§ 8:21-3A.2 Purpose

(a) The purpose of this subchapter is to:

1. Implement the requirements of the Federal Prescription Drug Marketing Act of 1987, 21 U.S.C. § 351, 353, 371 and 374, and 21 CFR 205 for the benefit of the health and safety of the ultimate consumers of prescription drugs;

2. Implement, as appropriate in New Jersey, the National Association of Boards of Pharmacy's "Model Rules for the Licensure of Wholesale Distributors (March 18, 2005)," available by written request to National Association of Boards of Pharmacy, 1600 Feehanville Drive, Mount Prospect, Illinois 60056, telephone (847) 391-4406, for the benefit of the health and safety of the ultimate consumers of drugs; and

3. Establish standards for the wholesale distribution of OTC and non-prescription drugs for the benefit of the health and safety of the ultimate consumers of OTC and non-prescription drugs.

§ 8:21-3A.3 Definitions

The words and terms used in this subchapter shall have the following meanings, unless the context clearly indicates otherwise:

"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. § 1504):

1. Is listed on the manufacturer's list of authorized distributors;

2. Has a written agreement currently in effect with the manufacturer; or

3. Has a verifiable account with the manufacturer and meets or exceeds the following transaction or volume requirement thresholds:

i. Five thousand sales units per company within 12 months; or

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

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Broker" means a person participating in the wholesale distribution of a drug that buys and sells the drug but does not take physical possession such that the drug is "sold to" the broker and "shipped to" a third party. A "broker only" cannot take possession of drugs under any circumstances.

"Contraband drug" means a drug which is counterfeit, stolen, misbranded, obtained by fraud, purchased by a non-profit institution for its own use and placed in commerce in violation of the own use agreement for that drug.

"Counterfeit drug" means a controlled substance, or other drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured distributed, or dispensed such substance and which thereby is falsely purported or represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser. A counterfeit drug shall include any counterfeit substance.

"Department" means the New Jersey Department of Health.

"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.

"Drug" shall have the meaning set forth at N.J.S.A. 24:1-1 and as used throughout this subchapter shall include both non-prescription and prescription drugs.

"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.

"Manufacturer" means anyone who is engaged in the manufacturing of drugs or devices, as defined in N.J.S.A. 24:6B-12, or engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug.

"Misbranded drug" shall be deemed to be misbranded if the label is false or misleading in any particular; or the label 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 in case of a drug; or do not show an accurate monograph for legend drugs; or other considerations as noted under N.J.S.A. 24:5-18 and in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq.

"Non-prescription" or "Non-legend" or "O.T.C." drugs mean drugs directly available to the consumer over the counter, without a physician's prescription.

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

"Readily available" and "readily retrievable" mean that records, either hard copy or computerized, are organized in such a manner that they can be quickly and easily retrieved during an inspection; individual records can be produced within minutes of the request. Required records that are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems are kept in such a manner so that they can be separated out from all other records in a reasonable time.

"Repackage" includes repacking or otherwise changing the container, wrapper, quantity, or labeling of a drug to further the distribution of the drug.

"Wholesale distribution" means the distribution of drugs or devices to persons other than a consumer or patient, but does not include:

1. Intracompany sales;

2. 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 or device for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

3. The sale, purchase, or trade of a drug or device or an offer to sell, purchase, or trade a drug or device 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;

4. The sale, purchase, or trade of a drug or device or an offer to sell, purchase, or trade a drug or device among hospitals or other health care entities that are under common control; for purposes of this definition "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;

5. The sale, purchase or trade of a drug or device or an offer to sell, purchase, or trade a drug or device for emergency medical reasons; for purposes of this definition, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

6. 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;

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

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

"Wholesale distributor" means anyone engaged in wholesale distribution of drugs including, but not limited to, manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; and independent wholesale drug traders, but does not include a retail pharmacy whose sales of prescription drugs to other than the ultimate user, including physicians for office use, nursing homes, institutions, etc. does not exceed five percent of the total gross annual sales of prescription drugs of the pharmacy.

§ 8:21-3A.4 Application requirements; reciprocity

(a) The Department may permit an out-of-State wholesale distributor to satisfy the registration requirements of this subchapter on the basis of reciprocity provided that such out-of-State wholesale distributor possesses a valid license or registration granted by another state pursuant to legal standards comparable to those which must be met by a registrant of this State as prerequisites for satisfying the registration requirements under the laws of this State.

(b) Every wholesale distributor of drugs shall apply to the Department in accordance with the provisions of N.J.S.A. 24:6B-2 using forms supplied by the Department. In addition, every applicant shall complete the appropriate sections of the application, which shall include:

1. Name, full business address and telephone number of the applicant;

i. All trade or business names used by the registrant;

ii. Addresses, telephone numbers and name of the contact person for all facilities used by the registrant for the storage, handling and distribution of drugs;

2. The type of ownership or operation (that is, partnership, corporation, or sole proprietorship);

3. The name(s) of the owner and/or operator of the applicant, including:

i. If a person, the name of the person, date and place of birth, the last four numbers of social security number and the Federal identification number;

ii. If a partnership, the name of each partner, date and place of birth, the last four numbers of social security number, the name of the partnership and the Federal identification number;

iii. If a corporation, the name, and title of each corporate officer and director, the corporate names, date and place of birth, the last four numbers of social security number, the name of the State of incorporation, and the Federal identification number, and

iv. If a sole proprietorship, the full name of the proprietor, date and place of birth, the last four numbers of social security number, the name of the business entity and the Federal identification number;

4. The address of each location in New Jersey at which the business is to be conducted. If an applicant's business is not to be conducted within the State, the application shall give the name and address of an agent resident of this State on whom process against the applicant may be served;

5. 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;

6. A description of the business;

7. The name and address of the individual or individuals on whom orders of the Commissioner may be served; and

8. A statement as to whether the registrant engages in the manufacturing, compounding, processing, wholesaling, jobbing, distribution of any controlled dangerous substances as defined pursuant to N.J.S.A. 24:21-2.

§ 8:21-3A.5 Evaluation criteria

(a) In considering any application for registration, the Department shall consider, at a minimum, the following factors in reviewing the qualifications of those persons applying for registration as a wholesale drug distributor:

1. Any convictions of the applicant under any Federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of a controlled substance;

2. Any felony conviction under Federal laws, or the equivalent (under whatever statutory term) conviction under state or local laws;

3. The applicant's past experience in the manufacturing or distribution of drugs or controlled substances;

4. The furnishing of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;

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

6. Compliance with license and/or registration requirements under any previously granted license or registration, if any;

7. Compliance with requirements to maintain and/or make available to the Department or Federal or local law enforcement officials those records required by this subchapter; and

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

(b) Wholesale drug distributors shall operate in compliance with applicable Federal, State and local laws and regulations and where the wholesale drug distributor also deals in controlled dangerous substances, it shall also register with the Department and Drug Enforcement Administration (DEA) and also comply with all applicable State rules and DEA regulations.

(c) A retail pharmacy wishing to conduct a wholesale business shall operate the wholesale business under a separate name and at a separate location, other than that of the pharmacy name and address and the wholesale business will be subject to all of the requirements of a wholesale distributor.

§ 8:21-3A.6 Denial of application

The Department shall have the right to deny an application for registration if it determines the granting of such registration would not be in the public interest or for submitting false information on an application. Public interest considerations shall be based upon factors and qualifications that are directly related to the protection of the public health and safety as delineated in N.J.A.C. 8:21-3A.5.

§ 8:21-3A.7 Personnel requirements

Personnel employed by a wholesale distributor shall have appropriate education and/or experience to assume responsibility for positions that would affect compliance with registration requirements.

§ 8:21-3A.8 Facility

(a) All facilities at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

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

2. Provide storage areas which include adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

3. Provide a quarantine area for storage of outdated, damaged, deteriorated, misbranded or adulterated drugs, or drugs that are in immediate or sealed secondary containers that have been opened;

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

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

§ 8:21-3A.9 Security

(a) All facilities used for wholesale distribution shall be secure from unauthorized entry and shall provide the following additional security measures:

1. Access from outside the premises shall be kept at a minimum and shall be well controlled;

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

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, and shall provide, when appropriate, protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

§ 8:21-3A.10 Storage

(a) All drugs shall be stored at appropriate temperature and conditions in accordance with the requirements set forth in the labeling of such drugs or with the requirements of the current edition of an official compendium, such as the United Pharmacopoeia/National Formulary (USP/NF).

(b) 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.

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

(d) For prescription drugs, a record must be maintained recording the date; time; thermometer temperature; and the initials of the person recording the data or reviewing the data if electronically monitored. This record and temperature reading must be recorded at least five days each week with the temperature readings taken between 1:00 P.M. and 5:00 P.M. E.S.T. Alternate times may be approved by the Department in writing. This record must be kept on file by the facility for at least two years.

§ 8:21-3A.11 Examination of materials

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of counterfeit, misbranded, contraband or contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution, and such examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents. If visual examination of the shipping container or other conditions surrounding the transaction suggest possible counterfeiting or contamination, the person has a duty to examine further the contents or conditions of sale.

(b) Each outgoing shipment of prescription drugs shall be carefully examined for the 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.

§ 8:21-3A.12 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) 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 the drug meets appropriate standards of safety, identity, strength, quality and purity. The wholesale distributor of prescription drugs shall consider, among other things, the conditions under which the drugs were held, stored, or shipped before or during their return and the condition of the drug and its container, carton, or labeling as a result of storage and shipping when considering that there is any doubt of the drug's safety, identity, strength, quality or purity.

§ 8:21-3A.13 Recordkeeping

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

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

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

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

4. Invoices that shall reflect the amount billed per prescription drug product; and

5. Inventory: A complete and accurate record of all stock of prescription drugs on hand must be made annually by wholesale distributors.

i. A physical inventory of prescription drugs must be conducted at least annually unless perpetual inventory records are maintained, in which case the physical inventory may be conducted on a biennial basis.

ii. If a wholesale distributor does not maintain a perpetual inventory, the annual physical inventory shall be retained for a period of three years following their creation date.

iii. Significant inventory discrepancies shall be investigated, and handled in accordance with written policies and procedures;

(b) Originals or true copies of required records documentation of drugs shall be maintained by the person involved in the transaction, including brokers and agents.

1. If electronic methods are used to maintain records related to drugs and these methods do not maintain a true copy of the original record, such as the actual image of the original document, then the security system of the wholesale distributor must provide protection against tampering with computers or electronic records.

2. Originals, true copies and electronical methods of records involving drugs shall be readily available and readily retrievable for inspection by an authorized State official and any other governmental agency charged with enforcement of these rules.

(c) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution, quarantine or other disposition of drugs.

(d) Wholesale distributors shall establish and maintain an ongoing listing of all retail and wholesale establishments with whom they purchase, acquire, sell, transfer, or dispose of drugs. At a minimum, this listing shall be updated monthly.

§ 8:21-3A.14 Due diligence

(a) Prior to the initial purchase or acquisition of prescription drugs from another wholesale distributor, a wholesale distributor shall obtain the following information from the selling wholesale distributor:

1. Copies of all state and Federal regulatory licenses and registrations;

2. The wholesaler distributor's most recent facility inspection reports;

3. A list of other names under which the wholesale distributor is doing business or by which the wholesale distributor was formally known;

4. A list of corporate officers and managerial employees and designated representative; and

5. A verification of the selling wholesale distributor's status as an authorized distributor of record, if applicable.

(b) At least annually, a wholesale distributor that purchases prescription drugs from another wholesale distributor shall update the information set forth in (a) above.

(c) No purchase shall take place from any storage facility, manufacturer or wholesale distributor not having a current license or registration within the jurisdiction of the establishment location from where product is purchased.

(d) No purchase or acquisition shall be permitted from a firm that has not provided complete information as set forth in (a) above.

§ 8:21-3A.15 Availability of records and inventories

(a) Records and inventories, including those related to any prescription drug salvage or reprocessing procedure, shall be made readily available and readily retrievable for inspection and photocopying by Federal, State or local law enforcement agencies shall be maintained for a period of three years following the disposition of the drugs.

(b) The records 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, and 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 enforcement agency.

§ 8:21-3A.16 Policies and procedures

(a) Wholesale prescription 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 inventory. Wholesale drug distributors shall include in their policy and procedures the following:

1. 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;

2. A procedure to be followed for, and which shall be adequate for, handling recalls and withdrawals due to:

i. Any action initiated by the request of the Food and Drug Administration or other Federal, state, local law enforcement or other government agency, including the State registering agency;

ii. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

iii. Any action undertaken to promote public health, and safety by replacing existing merchandise with an approved product or new package design.

3. A procedure to ensure that a wholesale distributor prepares for, protects against, and handles any crisis that affects security or the operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of a local, State or national emergency; and

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

§ 8:21-3A.17 List of responsible persons

Wholesale drug distributors shall maintain a list of officers, directors, managers, designated representative and other persons in charge of wholesale distribution, storage, and handling of prescription drugs that include a description of their duties and a summary of their qualifications.

§ 8:21-3A.18 Inspection and auditing

Wholesale drug distributors shall permit the Department 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.

§ 8:21-3A.19 Salvage; reprocessing

Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State or local laws, rules or regulations that relate to drug product salvaging or reprocessing.

§ 8:21-3A.20 Suspension; revocation

(a) The Department shall suspend or revoke any registration granted under this subchapter upon adjudication of civil liability or criminal conviction of the registrant of a violation of applicable Federal, State or local drug laws, rules or regulations.

(b) The Department may suspend or revoke any registration granted hereunder for any violation of this chapter, submitting false information on an initial or renewal application, falsification of records, or any good cause within the meaning and purpose of the law.

§ 8:21-3A.21 Penalties

The Department may provide for fines, imprisonment, or civil penalties as set forth in N.J.S.A. 24:6B-11 or 24:17.1.

§ 8:21-3A.22 Appeals

Prior to the suspension or revocation of a registration issued in accordance with this subchapter, the registrant shall have a right to prior notice and a hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules N.J.A.C. 1:1.

NJSA 24:6B

24:1-1. Definitions
As used in this Title:

e. "Drug" means (1) articles 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; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

g. "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

i. "New drug" means (1) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, and (2) any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

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.

L.1961,c.52,s.1; amended 2005, c.206, s.1.

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.

L.1961,c.52,s.2; amended 2005, c.206, s.1.

24:6B-3. Time for filing
A registration statement shall be filed prior to February 1 in each calendar year following the calendar year of original registration.

24:6B-4. Fee
A fee shall accompany each registration statement. It shall be $200.00 if the business has less than 2 locations in this State, and $500.00 if the business has 2 or more locations in this State; except that where the gross total annual business in drugs of a registrant shall not exceed 3% of the gross total annual volume of the business of the registrant, as certified by a certified public accountant, the fee shall be $50.00 for each location in this State.

L.1961, c. 52, p. 529, s. 4. Amended by L.1962, c. 110, s. 1, eff. July 16, 1962; L.1983, c. 275, s. 4, eff. July 18, 1983.

24:6B-5. Change of address; notice; fee
If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompany such notification.

L.1961, c. 52, p. 529, s. 5. Amended by L.1983, c. 275, s. 5, eff. July 18, 1983.

24:6B-6. Cleanliness of premises
Every room in the premises or place where drugs are manufactured, packaged or stored shall be kept clean and sanitary and shall be properly lighted, drained and ventilated. The walls and floors of such rooms shall be constructed of materials which can be properly cleaned and maintained. The operations carried on therein shall be conducted in a clean and sanitary manner so that the purity of the drugs therein manufactured, packaged or stored shall not be impaired.

24:6B-7. Cleanliness of equipment and machinery
Equipment and machinery used in the manufacture of drugs and any vehicles used for the transportation and delivery of such drugs shall be kept in a clean and sanitary condition.

L.1961, c. 52, p. 529, s. 7.

24:6B-8. Washroom and toilet facilities
Adequate washroom and toilet facilities shall be provided and maintained in the premise or place where drugs are manufactured, packaged or stored and such facilities shall be kept in a clean and sanitary condition.

L.1961, c. 52, p. 529, s. 8.

24:6B-9. Adulteration or misbranding of drug; examination of records
Whenever an officer or employee of the department finds, or has probable cause to believe, that any drug is adulterated or misbranded, he shall have the right to examine and copy any records listing the ingredients used in the manufacture of such drug and the source of such ingredients and any records concerning the storage or shipment of such drug to determine whether the provisions of this act or of subtitle 1 of Title 24 of the Revised Statutes relating to adulteration or misbranding are being complied with.

24:6B-10. Order to correct violation
If a registrant shall violate, directly or indirectly through his officers and employees, any of the provisions of this act, or any other provisions of subtitle 1 of Title 24 of the Revised Statutes, the commissioner may order the correction of the violation within such reasonable period of time as the commissioner may prescribe. Such an order shall be in writing, shall state the violation to be corrected,

the period of time within which such violation shall be corrected and the individual or individuals who have actual administrative responsibility who shall be responsible for having such correction made. The order shall be delivered in person or by certified mail to an individual designated to receive service of the commissioner's orders.

If the commissioner's order is not complied with within the period specified therein, or within any extension thereof, the commissioner may order the registrant to stop engaging in such business or the part affected by the order until the order is complied with. If the registrant shall continue such business or part thereof after the commissioner has ordered the registrant to stop, any individual designated responsible in the commissioner's order for correcting the violation shall be a disorderly person.

Any registrant ordered by the commissioner to stop engaging in business or any part thereof may appeal from such order to the Superior Court. Pending a hearing and determination upon the appeal, the court may stay execution of all or part of the commissioner's order.

L.1961, c. 52, p. 530, s. 11.

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.

L.1961,c.52,s.12;amended 1983, c.275, s.6; 2005, c.206, s.3.

24:6B-12 Definitions.

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

(a) "Commissioner" means Commissioner of Health or the commissioner's designated representative.

(b) "Department" means the Department of Health.

(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.

24:6B-13. Appropriation

There is hereby appropriated to the department so much of the revenue, not in excess of $25,000.00, derived from the registration fees as shall be required to administer this act during the fiscal year ending June 30, 1962.

L.1961, c. 52, p. 532, s. 14.

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.

"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 the 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.

"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; and 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, or 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.

L.2005, c.206, s.5; amended 2012, c.17, s.86.

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.

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

L.2005,c.206,s.7.

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.

L.2005,c.206,s.8.

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.

24:6B-19 Additional requirements for designated representatives.

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.

L.2005,c.206,s.10.

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.

L.2005,c.206,s.11.

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.

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.

L.2005,c.206,s.13.

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.

L.2005,c.206,s.14.

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.

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.

L.2005,c.206,s.16.

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.

L.2005,c.206,s.17.

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.

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.

L.2005,c.206,s.19.

24:6B-29 Violations, gradation 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, barters, 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.

L.2005,c.206,s.20.

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.

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.

L.2005,c.206,s.22.

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.

L.2005,c.206,s.23.

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.