24:6B-1

LEGISLATIVE HISTORY CHECKLIST

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LAWS OF: 2005 **CHAPTER:** 206

NJSA: 24:6B-1 (Establishes licensing requirements and standards for pharmaceutical wholesale distribution)

BILL NO: S1753 (Substituted for A3177)

SPONSOR(S): Vitale and Sarlo

DATE INTRODUCED: September 27, 2004

COMMITTEE: **ASSEMBLY:**
SENATE: Commerce

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: **ASSEMBLY:** June 27, 2005

SENATE: June 30, 2007

DATE OF APPROVAL: August 24, 2005

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (Senate Committee Substitute (2R) for S1753 enacted)

S1753

SPONSOR'S STATEMENT: (Begins on page 16 of original bill) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: No

SENATE: Yes

FLOOR AMENDMENT STATEMENT: Yes 2-14-2005
6-20-2005

LEGISLATIVE FISCAL ESTIMATE: No

A3177

SPONSOR'S STATEMENT: (Begins on page 16 of original bill) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: Yes

SENATE: No

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: No

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GOVERNOR'S PRESS RELEASE ON SIGNING: Yes

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REPORTS:	No
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See clippings for L.2005 c.205

IS 10/3/07

§§5-24 -
C.24:6B-14 to
24:6B-33
§25 - Note to §§1-24

P.L. 2005, CHAPTER 206, ***approved August 24, 2005***
Senate Committee Substitute ***(Second Reprint)*** for
Senate, No. 1753

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:

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

(cf: P.L.1961, c.52, s.1)

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

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 <u>non-prescription</u> 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

EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined <u>thus</u> is new matter.
Matter enclosed in superscript numerals has been adopted as follows:
[1] Senate floor amendments adopted February 14, 2005.
[2] Assembly floor amendments adopted June 20, 2005.

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.

(cf: P.L.1966, c.314, s.4)

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

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 **[**$200.00**]** $200 nor more than **[**$2,000.00**]** $5,000 and for the second and each succeeding offense for a penalty of not less than **[**$1,000.00**]** $1,000 nor more than **[**$10,000.00**]** $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" (N.J.S.2A:58-1 et seq.)**]** 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 **[**misdemeanor**]** disorderly persons offense.

(cf: P.L.1983, c.275, s.6)

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

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 **[**section**]** R.S. 24:1-1 **[**of the Revised Statutes**]**.

(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.

(cf: P.L.1961, c.52, s.13)

5. (New section) As used in sections 5 through 24 of P.L. , c. (C.) (pending before the Legislature as this bill):

"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 [2]or logistics provider[2]; 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.

[2]"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.[2]

"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.

[1][**[**"Pharmacy practice site" means any place in this State where drugs are dispensed or pharmaceutical care is provided by a licensed pharmacist, but shall not include a medical office under the control of a licensed physician.**]**[1]

"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 [1]**[**pharmacy practice sites**]** pharmacies[1], 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 [1]**[**pharmacy practice sites**]** pharmacies[1], 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[1]**[.]** ;[1]

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 [1][[]practice site[]][1], [2]logistics provider,[2] 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.

6. (New section) 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.

7. (New section) 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.

8. (New section) 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.

9. (New section) 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.

10. (New section) 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.

11. (New section) 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.

12. (New section) 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.

13. (New section) 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.

14. (New section) 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.

15. (New section) 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.

16. (New section) 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.

17. (New section) 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.

18. (New section) 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.

19. (New section) 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.

20. (New section) 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.

21. (New section) 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.

22. (New section) 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.

23. (New section) 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.

24. (New section) In accordance with the "Administrative Procedure Act," P.L.1968, c.410 (C.152:14B-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.

Establishes licensing requirements and standards for pharmaceutical wholesale distribution.

SENATE, No. 1753

STATE OF NEW JERSEY

211th LEGISLATURE

INTRODUCED SEPTEMBER 27, 2004

Sponsored by:
Senator JOSEPH F. VITALE
District 19 (Middlesex)
Senator PAUL SARLO
District 36 (Bergen, Essex and Passaic)

Co-Sponsored by:
Senator Buono

SYNOPSIS

Establishes licensing requirements and standards for pharmaceutical wholesale distribution.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 2/8/2005)

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:

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

(cf: P.L.1961, c.52, s.1)

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

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 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

EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined <u>thus</u> is new matter.

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.

(cf: P.L.1966, c.314, s.4)

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

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 $200.00 nor more than $2,000.00 and for the second and each succeeding offense for a penalty of not less than $1,000.00 nor more than $10,000.00. The penalties herein provided shall be enforced by the department as plaintiff in a summary proceeding in accordance with [the penalty enforcement law" (N.J.S. 2A:58-1 et seq.)] 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 misdemeanor.

(cf: P.L.1983, c.275, s.6)

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

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 section 24:1-1 of the Revised Statutes.

(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 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 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.**]**

(cf: P.L.1961, c.52, s.13)

5. (New section) As used in sections 5 through 7 and 9 through 20 of P.L. , c. (C.) (pending before the Legislature as this bill):

"Adulterated" means a drug or device that is adulterated pursuant to R.S.24:5-10. In addition, it refers to a drug or device for which the methods, facilities or controls used in its manufacture, processing, packing or holding do not conform to or are not administered in conformity with current good manufacturing practices to assure that the drug or device meets the requirements of P.L. , c. (pending before the Legislature as this bill).

"Authenticate" means to affirmatively verify before any distribution of a drug or device that each transaction listed on the pedigree, if a pedigree is required, and other accompanying documentation 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 products. An ongoing relationship is deemed to exist when the wholesale distributor:

a. has a written agreement currently in effect with the manufacturer evidencing an ongoing relationship; or

b. is listed on the manufacturer's current list of authorized distributors of record.

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

“Contraband" with respect to a drug or device 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 drug or device has been forged, counterfeited, falsely created, or contains any altered, false or misrepresented information.

“Counterfeit" with respect to a drug or device means a drug or device, 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 drug or device 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.

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

"Distribute" means to sell, offer to sell, deliver, offer to deliver, broker, give away or transfer a drug or device, whether by passage of title, physical movement, or both. The term does not mean:

a. to dispense or administer;

b. to deliver or offer to deliver in the usual course of business as a common carrier; or

c. to 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 acting at the direction of such a practitioner.

"FDA" means the federal Food and Drug Administration.

"Federal Act" means the Federal Food, Drug and Cosmetic Act, 21 U.S.C. s.301 et seq.

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

"Pedigree" means a document in written or electronic form approved by the commissioner that records each distribution of a drug or device, from the sale by a manufacturer though acquisition and sale by any wholesale distributor or repackager. A pedigree shall include the following information for each transaction:

a. the source of the drug, including the name and principal address of the seller;

b. the quantity of the drug, its dosage form and strength, date of purchase, sales invoice number, container size, number of containers and lot number;

c. the business name and address of each owner of the drug, and each owner's shipping information, including the address of the facility where each person certified delivery and receipt of the drug and the name of each person who made such certification;

d. a statement by the wholesale distributer that it has conducted due diligence of the wholesale distributor from which it purchased or may have purchased the drug; and

e. certification made under penalty of perjury, from the designated representative of the wholesale distributor that the information contained in the pedigree is true and accurate.

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

"Specified list of susceptible products" means a specific list of drugs or devices, to be determined by the commissioner, that are susceptible

to adulteration, counterfeiting or diversion and thereby pose a potential public health risk.

"USP" means the United States Pharmacopeia.

"Wholesale distribution" means the distribution of drugs or devices by a wholesale distributor to a person other than a consumer or patient and includes transfers of drugs from one pharmacy to another pharmacy if the value of the goods transferred exceeds 5% of total drug sales revenue of either the transferor or transferee pharmacy during any consecutive 12-month period. The term does not mean:

a. the sale, purchase, trade or dispensing of a drug or device pursuant to a prescription;

b. the transfer of a drug or device for emergency medical reasons such as transfers to alleviate a temporary shortage; sales to emergency medical services or licensed practitioners for use in the treatment of acutely ill or injured persons; and the provision of minimal emergency supplies of drugs to nearby nursing homes during hours when necessary drugs cannot be obtained;

c. intracompany transactions that do not violate own use provisions;

d. the sale, purchase or trade of a drug or device, or offer to sell, purchase or trade a drug or device among hospitals or other health care entities that are under common control or are members of the same group purchasing organization;

e. the sale, purchase or trade of a drug or device, or offer to sell, purchase or trade a drug or device 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;

f. the transfer of drugs or devices between pharmacies pursuant to a centralized prescription processing agreement; or

g. the distribution of drug samples by manufacturers' representatives or wholesale distributors' representatives.

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

6. (New section) a. A wholesale distributor engaged in the wholesale distribution of drugs or devices 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.

b. A wholesale distributor shall renew its license annually, and pay such license fees as established by the commissioner.

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, which shall not be identical to any name used by another wholesale distributor licensed in this State;

(2) the name, 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 name of the partnership and federal employer identification number;

(b) if a corporation, the name, 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, 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; and

(3) the name, address and telephone number of each person who shall serve as the designated representative as provided in section 10 of P.L. , c. (C.)(pending before the Legislature as this bill).

d. An applicant shall obtain a surety bond of not less than $100,000, or other equivalent means of security, as determined by the commissioner, to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding the license. The department may make a claim against such bond or 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, including an appeal, before or on behalf of the department involving the wholesale distributor.

e. A licensed wholesale distributor located outside of this State who distributes drugs in this State shall 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 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.

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

the department.

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

7. (New section) The commissioner is authorized to require an applicant, designated representative and any person enumerated in subsection c. of section 6 of P.L. , c. (C.)(pending before the Legislature as this bill) to undergo a criminal history record background check for the purposes of determining eligibility for licensure, and to submit such information as is necessary to conduct the background check. The background check shall be conducted in compliance with applicable State and federal laws, at the applicant's expense, and include all states of residence since the applicant has been an adult. The commissioner is authorized to exchange fingerprint data with and receive criminal history record information from the State Bureau of Identification in the Division of State Police and the Federal Bureau of Investigation.

8. (New section) A manufacturer that is registered with the department shall establish and update on a monthly basis a list of its authorized distributors and authorized distributors of record. The list shall be filed with the department, which shall publish the list on its website.

9. (New section) a. The department shall determine eligibility for, and renewal of, licensure of persons engaged in the wholesale distribution of drugs and devices. 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 and applicant's eligibility:

(1) 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 or devices;

(2) The results of criminal history record background checks of: the applicant, designate representative and such other persons as specified in subsection c. of section 6 of P.L. , c. (C.)(pending before the Legislature as this bill) .

(3) The applicant's past experience in the manufacturing or distribution of drugs or devices;

(4) Whether the applicant furnished false or fraudulent material in any application related to drug or device manufacturing or distribution; and

(5) Compliance with previously granted licenses of any kind.

b. The applicant shall provide, and attest to, a statement disclosing

any past criminal convictions and violations of state and federal laws regarding drugs or devices.

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

(1) Submit an application that includes the following information:

(a) his date and place of birth;

(b) occupations, positions of employment, and offices held during the past seven years, and the principal business addresses;

(c) whether he has been temporarily or permanently enjoined by a court of competent jurisdiction during the past seven years for violating any federal or state law regulating drugs or devices, together with details of such events;

(d) a description of any involvement with any business which manufactured, administered, prescribed, distributed or stored drugs or devices and which was named as a party in a lawsuit;

(e) a description of any criminal offense, excluding minor traffic violations, of which he, as an adult, was found or plead guilty. If the person indicates that a criminal conviction is under appeal, he shall submit a copy of the notice of appeal, and within 15 days after the disposition of the appeal, submit a copy of the final written order of disposition;

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

(g) the name, address, occupation, date and place of birth for each member of his immediate family. For purposes of this subsection, immediate family includes spouse, children, parents, siblings and the spouses of the children and siblings; and

(2) Have a minimum of two years of verifiable, full-time managerial or supervisory experience with a pharmacy or wholesale distributor licensed in this or another state, where responsibilities included record keeping, storage and shipment of drugs or devices;

(3) Serve as the designated representative for only one wholesale distributor at any one time;

(4) Be actively involved in and aware of the actual daily operations of the wholesale distributor. Active involvement means 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; and

(5) Complete continuing education programs specified by the commissioner regarding federal and State laws relevant to the distribution of drugs and devices.

b. Any additional personnel engaged in the operation and handling of drugs or devices shall possess the education and experience

necessary to safely and lawfully engage in the wholesale distribution of drugs.

11. (New section) All facilities used for wholesale drug distribution shall:

a. be of suitable construction to ensure that all drugs and devices in the facilities are maintained in accordance with labeling of such drugs and devices, or in compliance with 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 drugs and devices that are adulterated, counterfeit or suspected counterfeit, or otherwise unfit for distribution;

e. be maintained in a clean and orderly condition;

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

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

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

12. (New section) A wholesale distributor shall:

a. provide a pedigree for the wholesale distribution of drugs before the transaction to another wholesale distributor in accordance with the record keeping provisions of section 17 of P.L. , c. (C.) (pending before the Legislature as this bill);

b. 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. be duly registered with the federal Drug Enforcement Administration and the department; and

d. possess and maintain in good working order equipment that meets standards set by the commissioner and allows the wholesale distributor to authenticate, track and trace drugs or devices. The equipment shall be used to conduct for-cause and random tracking, tracing, and authentication of drugs or devices, pursuant to section 13 of P.L. , c. (C.) (pending before the Legislature as this bill).

13. (New section) a. (1) A wholesale distributor shall authenticate every distribution of a drug or device back to the manufacturer if he

has reason to believe that any drug or device purchased from another wholesale distributor is adulterated, misbranded, counterfeit or suspected of being counterfeit, or otherwise unfit.

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

(3) If a wholesale distributor is unable to authenticate each transfer, he shall quarantine the drug or device and report this to the department and FDA within 10 business days after completing the attempted authentication.

(4) If the wholesale distributor satisfactorily completes the authentication, he shall maintain records of the authentication for three years, and produce them to the department and FDA upon request.

b. (1) A wholesale distributor who purchases drugs or devices from other wholesale distributors shall, at least annually, conduct random authentications of pedigrees on at least 10% of sales units of drugs or devices purchased from other wholesale distributors.

(2) A wholesale distributor shall, at least quarterly, conduct random authentications of pedigrees on at least 90% of sales units of drugs or devices purchased from other wholesale distributors if the drugs or devices are on the department's specified list of susceptible products.

(3) Wholesale distributors from whom other wholesale distributors have purchased drugs or devices shall cooperate with random authentications of pedigrees and provide requested information in a timely manner.

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

c. Upon receipt of a shipping container, a wholesale distributor shall review records for the acquisition of drugs or devices 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.

15. (New section) a. Any drug or device that was ordered in error or in excess of need by the wholesale distributor shall be returned to the manufacturer or wholesale distributor from which it was acquired, provided that three business days have not passed, the integrity of the drug or device has been maintained and appropriate documentation is made to the pedigree.

b. Any drug or device, or any container or labeling that is outdated, damaged, deteriorated, misbranded, counterfeited, suspected of being counterfeited, adulterated, or otherwise deemed unfit for human consumption shall be quarantined until it is returned to the manufacturer or wholesale distributor from which it was acquired. Notice shall be provided to the department, FDA and manufacturer or wholesale distributor from which it was acquired within three business days.

c. Any drug or device that has been opened or used, but is not adulterated, misbranded, counterfeited, or suspected of being counterfeit, shall be so identified and quarantined until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired.

d. If any condition under which a drug or device has been returned casts doubt on its safety, identity, strength, quality or purity, then the drug or device shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug or device meets appropriate standards of safety, identity, strength, quality and purity.

e. Contraband, counterfeit, or suspected counterfeit drugs and devices, evidence of criminal activity and accompanying documentation shall be retained until its disposition is authorized by the department and the FDA. 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 shall not be destroyed until its disposition is authorized by the department and FDA.

16. (New section) A wholesale distributor shall exercise due diligence in accordance with the following requirements, unless the commissioner waives any requirement:

a. Prior to the first purchase of drugs from another wholesale distributor, the purchasing wholesale distributor shall obtain the following information from the selling wholesale distributor:

(1) A list of states in which the wholesale distributor is licensed, and into which it ships drugs or devices ;

(2) Copies of all State and federal regulatory licenses and registrations;

(3) The wholesale distributor’s most recent facility inspection reports;

(4) Copies of relevant general and product liability insurance policies;

(5) A list of any other names under which the wholesale distributor does business or was formerly known;

(6) Names of corporate officers and managerial employees;

(7) Names of all persons who own more than 10% of the wholesale distributor, unless the wholesale distributor is publicly traded;

(8) A list of all disciplinary actions by state and federal agencies;

(9) A description, including the address, dimensions, and other relevant information, of each facility used for drug storage and distribution;

(10) A description of drug import and export activities of the wholesale distributor;

(11) A description of the wholesale distributor's process to comply with this act; and

(12) A statement whether and for whom the wholesale distributor is an authorized distributor of record.

b. Prior to the first purchase of drugs from another wholesale distributor, the purchasing wholesale distributor shall:

(1) verify the selling wholesale distributor's status as an authorized distributor of record, if applicable; and

(2) conduct, or engage a third party to conduct, an inspection of the wholesale distributor's facility if the facility has not been inspected by the department within three years of the contemplated purchase to ensure compliance with applicable laws and regulations relating to the storage and handling of drugs or devices.

c. At least annually, a wholesale distributor who purchases drugs from another wholesale distributor shall update the information required pursuant to section 17 of P.L. , c. (C.)(pending before the Legislature as this bill).

d. At least once every three years, a wholesale distributor who purchases drugs or devices from another wholesale distributor shall inspect, or engage a third party to inspect, the facility or facilities of the wholesale distributor from whom it is purchasing drugs as set forth in section 17 of P.L. , c. (C.) (pending before the Legislature as this bill), unless the facility has been inspected by the department within the last three years.

17. (New section) a. A wholesale distributor shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of drugs or devices. Such records shall include:

(1) If an authorized distributor, pedigrees for drugs distributed that are included on the department's list of susceptible products; or

(2) If not an authorized distributor, pedigrees for all drugs that are distributed.

b. Effective January 1, 2007, all wholesale distributors, whether located in or out-of-State, whether an authorized distributor or not, shall maintain an electronic pedigree in accordance with standards and requirements established by the department, for all drugs received and distributed.

c. Records maintained pursuant to this section shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of the department. Records shall be made available for inspection for three years following their creation.

d. A wholesale distributor shall establish and maintain procedures for reporting to the department and FDA the existence of counterfeit or suspected counterfeit drugs or devices or counterfeiting or suspected counterfeiting activities, and significant shortages or losses of drugs or devices where diversion is known or suspected.

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

a. A procedure for handling recalls and withdrawals of drugs or devices;

b. A procedure to prepare for and protect against any crisis that affects security or operation of any facility;

c. A procedure for segregating, returning and destroying drugs and devices, and providing all necessary documentation;

d. A procedure for disposing and destruction of containers, labels, and packaging to ensure that they cannot be used in counterfeiting activities;

e. A procedure for investigating and reporting inventory discrepancies;

f. A procedure for timely reporting of criminal or suspected criminal activities to the department;

g. A procedure for conducting the for cause and random pedigree authentications in exercising due diligence required by section 16 of P.L. , c. (C.) (pending before the Legislature as this bill).

19. (New section) a. A person who engages in the wholesale distribution of drugs or devices and, with intent to defraud or deceive, fails to deliver to another person complete and accurate pedigree, when required, prior to transferring the drug or device to another

person, is guilty of a crime of the third degree.

b. A person who engages in the wholesale distribution of drugs or devices, and with intent to defraud or deceive, fails to acquire complete and accurate pedigree, when required, concerning a drug or device prior to obtaining the drug or device from another person, is guilty of a crime of the third degree.

c. A person who engages in the wholesale distribution of drugs or devices, and knowingly destroys, alters, conceals or fails to maintain complete and accurate pedigree concerning any drug or device in his possession, is guilty of a crime of the third degree.

d. A person who engages in the wholesale distribution of drugs or devices, who possesses pedigree documents required by the department, and knowingly fails to authenticate the matters contained in the documents as required, and nevertheless distributes or attempts to further distribute drugs or devices, is guilty of a crime of the third degree.

e. A person who engages in the wholesale distribution of drugs or devices, and with intent to defraud or deceive, falsely swears or certifies that he has authenticated any documents related to the wholesale distribution of drugs or devices, is guilty of a crime of the third degree.

f. A person who engages in the wholesale distribution of drugs or devices, and knowingly forges, counterfeits, or falsely creates any pedigree, who falsely represents any factual matter contained on any pedigree, or who knowingly omits to record material information required to be recorded in a pedigree, is guilty of a crime of the third degree.

g. A person who engages in the wholesale distribution of drugs or devices, and knowingly purchases or receives drugs or devices from a person not authorized to distribute drugs or devices in wholesale distribution, is guilty of a crime of the third degree.

h. A person who engages in the wholesale distribution of drugs or devices, and knowingly sells, barters, brokers, or transfers drugs or devices to a person not authorized to purchase drugs or devices, under the jurisdiction in which the person receives the drugs or devices in a wholesale distribution, is guilty of a crime of the third degree.

i. A person who knowingly possesses, actually or constructively, any amount of a contraband drug or device, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of a contraband drug or device, is guilty of a crime of the third degree.

j. A person who knowingly forges, counterfeits or falsely creates any label for a drug or device or who falsely represents any factual matter contained in any label of a drug or device is guilty of a crime of the third degree.

k. A person who knowingly manufactures, purchases, sells, delivers or brings into the State, or who is knowingly in actual or constructive

possession of any amount of contraband drugs or devices, is guilty of a crime of the third degree.

l. 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 contraband drugs or devices, and whose acts result in the death of a person, is guilty of a crime of the first degree.

20. (New section) a. A court convicting and sentencing a defendant found guilty of a crime under section 19 of P.L. , c. (C.) (pending before the Legislature as this bill) shall order the defendant to forfeit to the State any real or personal property which was used or intended to be used to commit, facilitate or promote the commission of such crime or which constitutes, is derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the crime.

b. Any property or assets subject to forfeiture under subsection a. of this section may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise permitted by law.

c. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited shall be equitably divided between the department and other agencies involved in the investigation and prosecution which led to the conviction. Other property ordered forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the department or the agencies involved in the investigation and prosecution which led to the conviction.

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

22. This act shall take effect on the 180th day after enactment, except that the commissioner may take such anticipatory administrative action in advance as shall be necessary for the implementation of the act.

STATEMENT

The purpose of this bill is to promote the safety and effectiveness of prescription drugs and devices distributed in this State.

N.J.S.A.24:6B-1 et seq., which currently governs the licensure of both drug manufacturers and wholesale distributors, is amended in to

eliminate references to wholesale distributors, and the balance of this bill establishes a separate, comprehensive scheme for regulating wholesale distributors.

The bill requires that wholesale distributors engaged in the wholesale distribution of drugs and devices within this State, whether or not located within this State, be licensed by the Department of Health and Senior Services. The license would be renewed annually and the commissioner would determine reasonable fees for licensure and renewal.

An applicant for licensure would be required to undergo a criminal history record background check and to provide detailed information such as names, addresses, social security numbers, and dates of birth of owners, operators and key personnel, and depending on the legal form of the entity, other information about the principals involved in the entity. A surety bond of not less than $100,000, or other equivalent means of security, would be required to secure payment of any unpaid fees, costs or administrative penalties. The applicant's facility would undergo an inspection by the department prior to initial licensure, and periodically thereafter, at least once every three years.

The bill sets forth the minimum qualifications to be considered by the department in determining eligibility for licensure, but the Commissioner of Health and Senior Services may add any qualifications that he deems relevant to protecting the public health and safety. Factors to be considered in determining an applicant's eligibility include:

- suspension, sanction, or revocation of any license for violations of laws regarding drugs or devices;

- results of a criminal history record background checks;

- the applicant's past experience in the manufacture and distribution of drugs or devices;

- whether the applicant furnished false or fraudulent material in any application made in connection with drug or device manufacturing or distribution; and

- compliance with previously granted licenses of any kind.

The bill requires that a wholesale distributor designate a representative who is actively involved in and aware of its daily operations. The designated representative would be required to provide to the department detailed information, including:

- occupations, offices and positions of employment held during the past seven years;

- whether he has been temporarily or permanently enjoined by a court of competent jurisdiction during the past seven years for violating any federal or state law regulating drugs or devices;

- a description of any involvement during the previous seven years with any business which manufactured, distributed or stored drugs or devices and which was named as a party in a lawsuit;

- a description of any criminal offense, excluding minor traffic violations;

- a recent photograph of the person; and

- the name, address, occupation, date and place of birth for each member of the person's family, including the person's spouse, children, parents, siblings, and the spouses of the person's children and siblings.

The proposed designated representative would also be required to have a minimum of two years of verifiable, full-time managerial or supervisory experience with a pharmacy or wholesale distributor licensed in this State or another state. A designated representative would be permitted to serve only one wholesale distributor at a time, and would be required to complete continuing education programs specified by the commissioner.

All facilities used for wholesale drug distribution would have to meet standards of cleanliness, and be equipped with appropriate security systems that protect against theft, diversion and counterfeiting. The bill establishes minimum requirements for the proper storage, handling and shipment of drugs and devices, and mandates that records be maintained regarding these activities. The bill also requires that a wholesale distributor establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, transport and shipping and distribution of drugs.

A significant security and anti-counterfeiting measure in the bill is the pedigree requirement. "Pedigree" is defined as a document in written or electronic form that records each distribution of a drug or device, from the sale by a manufacturer though acquisition and sale by any wholesale distributor or repackager. A pedigree would include the following information with respect to each transaction:

- the quantity of the drug, its dosage form and strength, date of purchase, sales invoice number, container size, number of containers and lot number;

- the business name and address of each owner of the drug, and each owner's shipping information; and

- a statement by the wholesale distributer that it has conducted due diligence of the wholesale distributor from which it purchased or may have purchased the drug.

Effective January 1, 2007, all wholesale distributors will be required to establish and maintain an electronic pedigree system that meets the standards and requirements of the department.

The bill would require a wholesale distributor to possess and maintain in good working order technology and equipment that allows for authentication, and tracking and tracing of drugs or devices. The bill requires that two types of authentication be conducted: "for cause" authentication and "random" authentication. A wholesale distributor would be required to authenticate a drug or device back to the manufacturer if there is reason to believe that any drug or device

purchased from another wholesale distributor is counterfeit, suspected of being counterfeit, misbranded or adulterated.

In addition, random authentications would be required at least annually on at least 10% of sales units of drugs or devices purchased from other wholesale distributors. A wholesale distributor would also be required to conduct quarterly random authentications of pedigrees on at least 90% of sales units of drugs or devices purchased from other wholesale distributors that are on the department's specified list of susceptible products.

The bill also requires that a wholesale distributor visually examine each shipping container upon receipt to confirm its identity and determine if it may contain contaminated, contraband, counterfeit or damaged drugs or devices, or drugs or devices that are otherwise unfit for distribution. Any drugs or devices found to be unacceptable would be quarantined until further examination determines that the drugs or devices are fit. A drug or device whose container or label is adulterated, misbranded, counterfeited, or suspect of being counterfeit would be quarantined as well. Notice of any quarantine would be provided to the department, the FDA and the manufacturer or wholesale distributor from which it was acquired within three business days. Each outgoing shipment would be inspected to ensure that drugs or devices have not been damaged or held under improper conditions while in storage.

The bill also establishes due diligence requirements of wholesale distributors, which the commissioner is authorized to waive when appropriate. Due diligence requirements include investigating the following:

- a list of states the wholesale distributor is licensed in, and into which it ships drugs;

- copies of all State and federal regulatory licenses and registrations;

- the wholesale distributor's most recent facility inspection reports;

- information regarding general and product liability insurance, including copies of relevant policies;

- a list of other names under which the wholesale distributor is doing business, or was formerly known;

- a list of corporate officers and managerial employees;

- a list of all persons who own more than 10% of the wholesale distributor, unless the wholesale distributor is publicly traded;

- a list of all disciplinary actions by state and federal agencies;

- detailed information about each facility or warehouse used for drug storage and distribution;

- a description of drug import and export activities of the wholesale distributor;

- a description of the wholesale distributor's process to comply with this bill; and

- a statement as to whether and for whom the wholesale distributor is an authorized distributor of record.

The bill's extensive record-keeping provisions require that a wholesale distributor establish and maintain detailed records of all transactions regarding the receipt, distribution or other disposition of drugs or devices. These records include pedigrees for drugs distributed that are included on the specified list of susceptible products if acquired from an authorized distributor, and if the acquisition is not from an authorized distributor, pedigrees for all drugs that are distributed.

Finally, the bill contains the following criminal provisions:

A person commits a crime of the third degree if he:

-engages in the wholesale distribution of drugs or devices and, with intent to defraud or deceive, fails to deliver to another person complete and accurate pedigree, when required, concerning a drug or device prior to transferring the drug or device to another person;

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

-engages in the wholesale distribution of drugs or devices and knowingly destroys, alters, conceals, or fails to maintain complete and accurate pedigree concerning any drug or device in his possession;

-engages in the wholesale distribution of drugs or devices and is in possession of drug pedigree documents required by the department and, knowingly fails to authenticate the matters contained in the documents as required and nevertheless distributes or attempts to further distribute drugs or devices;

-engages in the wholesale distribution of drugs or devices and, with intent to defraud or deceive, falsely swears or certifies that he has authenticated any documents related to the wholesale distribution of drugs or devices;

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

- engages in the wholesale distribution of drugs or devices and knowingly purchases or receives drugs or devices from a person not authorized to distribute drugs or devices in wholesale distribution;

- engages in the wholesale distribution of drugs or devices and knowingly sells, barters, brokers, or transfers drugs or devices to a person not authorized to purchase drugs or devices, under the jurisdiction in which the person receives the drugs or devices in a wholesale distribution;

- knowingly possesses, actually or constructively, any amount of

contraband drugs or devices, and knowingly sells or delivers, or possesses with intent to sell or deliver, any amount of a contraband drug or device;

-knowingly forges, counterfeits, or falsely creates any label for a drug or device, or falsely represents any factual matter contained in any label of a drug or device; or

-knowingly manufactures, purchases, sells, delivers or brings into the State, or is knowingly in actual or constructive possession of any amount of contraband drugs or devices;

A person commits a crime of the first degree if he knowingly manufactures, purchases, sells, delivers or brings into the State, or is knowingly in actual or constructive possession of any amount of contraband drugs or devices, and his acts result in the death of a person.

A person found guilty of any of the above offenses shall be ordered to forfeit to the State any real or personal property used or intended to be used to commit, facilitate or promote the commission of the offense, as well as property derived from, or traceable to the gross proceeds obtained directly or indirectly as a result of the offense. Forfeited monies or other assets ordered forfeited shall be equitably divided between the department and other agencies involved in the investigation and prosecution which led to the conviction.

SENATE COMMERCE COMMITTEE

STATEMENT TO

SENATE COMMITTEE SUBSTITUTE FOR
SENATE, No. 1753

STATE OF NEW JERSEY

DATED: FEBRUARY 7, 2005

The Senate Commerce Committee reports favorably a Senate Committee Substitute for Senate Bill No. 1753.

This bill, the Senate Committee Substitute for Senate Bill No. 1753, establishes a new regulatory scheme for the licensure of wholesale distributors of prescription drugs by the Department of Health and Senior Services (DHSS).

The bill amends the current law governing the licensure of both manufacturers and wholesale drug distributors, to specify that it applies to manufacturers, and to wholesale distributors of non-prescription drugs only. In addition, the maximum penalties that may be imposed for failure to comply with an order of the Commissioner of DHSS under that law are increased from $2,000 to $5,000 for the first offense, and from $10,000 to $20,000 for the second and subsequent offenses.

Specifically, the substitute bill provides as follows:

- A wholesale distributor must be licensed annually by DHSS. DHSS, or an appropriate third party contractor, shall inspect the applicant's facility prior to initial licensure, and at least once every three years thereafter.
- An applicant for licensure is required to undergo a criminal history record background check and provide detailed information on owners, operators and key personnel, who may also be subject to criminal history record background checks.
- Unless waived by the commissioner, an applicant must post a surety bond or other equivalent means of security -- at least $100,000 for businesses with over $10,000,000 in annual gross receipts and $25,000 for businesses with $10,000,000 or less in annual gross receipts.
- A wholesale distributor is required to designate a representative, who may serve only one wholesale distributor at a time. A designated representative is required to be actively involved in daily operations and have at least two years of verifiable relevant experience.
- All facilities used for wholesale prescription drug distribution are required to meet standards of cleanliness and be equipped with appropriate security systems.

- The bill establishes minimum requirements for the proper storage, handling and shipment of prescription drugs, and mandates that written policies, procedures and records be maintained regarding these activities.
- The significant security and anti-counterfeiting measure in this bill is the pedigree requirement, which documents each transaction involved in the distribution of a prescription drug. A pedigree would include information with respect to each transaction, specifically: the quantity of the prescription drug; its dosage form and strength; date of purchase; sales invoice number; container size; number of containers; name and address; and shipping information of each owner of the prescription drug.
- The commissioner is required to report to the Legislature on the status of electronic tracking technology that would effectively deter and detect counterfeiting of prescription drugs. If he determines that it is feasible to implement an industry-wide system that could replace current tracking practices, he is to recommend how and when such a system could be implemented.
- A wholesale distributor must undertake two types of authentication of distributions of a prescription drug: "for cause" and "random" authentications. A prescription drug must be authenticated back to the manufacturer if there is reason to believe that it is counterfeit, misbranded or adulterated. Random authentications are required at least annually on at least 10% of sales units of prescription drugs purchased from other wholesale distributors, and on at least 90% of sales units of prescription drugs purchased from other wholesale distributors that are on the DHSS "specified list of susceptible products," which is also required pursuant to the bill.
- A wholesale distributor is required to visually examine each shipping container upon receipt to confirm its identity and determine if it may contain contaminated, contraband, counterfeit or damaged prescription drugs. A wholesale distributor shall also ensure that each outgoing shipment of prescription drugs was not damaged or held under improper conditions while in storage.
- A manufacturer or wholesale distributor who receives returned prescriptions is required to notify DHSS of the return.
- The bill also establishes due diligence requirements for wholesale distributors, which the commissioner is authorized to waive when appropriate. Due diligence requires obtaining detailed information from a selling wholesale distributor, including information regarding: the state in which the wholesale distributor is domiciled and into which it ships prescription drugs; its most recent facility inspection reports; relevant insurance coverage; other names under which the wholesale distributor does or did business; the corporate officers and managerial employees; disciplinary actions by state and federal agencies for the last four years, if the selling wholesale distributor supplies it upon request by the purchasing wholesale

distributor; and information about each facility or warehouse used for prescription drug storage and distribution.

- The bill's extensive record-keeping provisions require that a wholesale distributor establish and maintain detailed records of all transactions regarding the receipt, distribution or other disposition of prescription drugs.
- Certain criminal sanctions are included among the bill's provisions: (1) A person commits a crime of the third degree if the person engages in any of several enumerated offenses involving the wholesale distribution, possession or manufacture of prescription drugs; (2) A person commits a crime of the first degree if the person 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 those actions result in the death of a person; (3) A person who engages in the wholesale distribution of prescription drugs without having registered with DHSS as required by this bill is guilty of a disorderly persons offense.
- The bill also provides for civil penalties for failure to comply with an order of the commissioner, ranging from $200 to $5,000 for the first offense, and from $1,000 to $20,000 for the second and subsequent offenses.
- A person found guilty of any of the above offenses may be ordered to forfeit to the State any real or personal property.
- Finally, the bill establishes an eight-member Wholesale Drug Distribution Advisory Council in DHSS to consider proposed regulations on the distribution of prescription drugs and to recommend measures that may improve the integrity of the prescription drug distribution system. The members are to include: the commissioner and the Director of the Division of Consumer Affairs in the Department of Law and Safety, or their designees; and representatives of wholesale distributors, prescription drug manufacturers, pharmacies and chain pharmacies.
- The bill takes effect on the 180th day after enactment, but authorizes the commissioner to take anticipatory administrative action as necessary for its implementation.

STATEMENT TO

SENATE COMMITTEE SUBSTITUTE FOR

SENATE, No. 1753

with Senate Floor Amendments
(Proposed By Senator SARLO)

ADOPTED: FEBRUARY 14, 2005

This amendment removes the definition of the term "pharmacy practice site" from the bill and eliminates its usage in the bill, to clarify that the bill's provisions apply to pharmacies, as that term is customarily used and understood.

STATEMENT TO

[First Reprint]

SENATE COMMITTEE SUBSTITUTE FOR
SENATE, No. 1753

with Assembly Floor Amendments
(Proposed by Assemblyman SCALERA)

ADOPTED: JUNE 20, 2005

This amendment adds the definition "logistics provider," and exempts entities so defined from the requirements of the bill. Under the amendments, "logistics provider" is defined as 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.

[Corrected Copy]

ASSEMBLY, No. 3177

STATE OF NEW JERSEY

211th LEGISLATURE

INTRODUCED SEPTEMBER 13, 2004

Sponsored by:
Assemblyman FREDERICK SCALERA
District 36 (Bergen, Essex and Passaic)
Assemblywoman LINDA R. GREENSTEIN
District 14 (Mercer and Middlesex)

Co-Sponsored by:
Assemblywoman Voss

SYNOPSIS

Establishes licensing requirements and standards for pharmaceutical wholesale distribution.

CURRENT VERSION OF TEXT

As introduced.

(Sponsorship Updated As Of: 10/22/2004)

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:

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

(cf: P.L.1961, c.52, s.1)

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

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 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

EXPLANATION - Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined <u>thus</u> is new matter.

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.

(cf: P.L.1966, c.314, s.4)

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

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 $200.00 nor more than $2,000.00 and for the second and each succeeding offense for a penalty of not less than $1,000.00 nor more than $10,000.00. The penalties herein provided shall be enforced by the department as plaintiff in a summary proceeding in accordance with [the penalty enforcement law" (N.J.S.2A:58-1 et seq.)] 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 misdemeanor.

(cf: P.L.1983, c.275, s.6)

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

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 section 24:1-1 of the Revised Statutes.

(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 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 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.**]**

(cf: P.L.1961, c.52, s.13)

5. (New section) As used in sections 5 through 7 and 9 through 20 of P.L. , c. (C.) (pending before the Legislature as this bill):

"Adulterated" means a drug or device that is adulterated pursuant to R.S.24:5-10. In addition, it refers to a drug or device for which the methods, facilities or controls used in its manufacture, processing, packing or holding do not conform to or are not administered in conformity with current good manufacturing practices to assure that the drug or device meets the requirements of P.L. , c. (pending before the Legislature as this bill).

"Authenticate" means to affirmatively verify before any distribution of a drug or device that each transaction listed on the pedigree, if a pedigree is required, and other accompanying documentation 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 products. An ongoing relationship is deemed to exist when the wholesale distributor:

a. has a written agreement currently in effect with the manufacturer evidencing an ongoing relationship; or

b. is listed on the manufacturer's current list of authorized distributors of record.

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

“Contraband" with respect to a drug or device 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 drug or device has been forged, counterfeited, falsely created, or contains any altered, false or misrepresented information.

“Counterfeit" with respect to a drug or device means a drug or device, 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 drug or device 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.

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

"Distribute" means to sell, offer to sell, deliver, offer to deliver, broker, give away or transfer a drug or device, whether by passage of title, physical movement, or both. The term does not mean:

a. to dispense or administer;

b. to deliver or offer to deliver in the usual course of business as a common carrier; or

c. to 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 acting at the direction of such a practitioner.

"FDA" means the federal Food and Drug Administration.

"Federal Act" means the Federal Food, Drug and Cosmetic Act, 21 U.S.C. s.301 et seq.

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

"Pedigree" means a document in written or electronic form approved by the commissioner that records each distribution of a drug or device, from the sale by a manufacturer though acquisition and sale by any wholesale distributor or repackager. A pedigree shall include the following information for each transaction:

a. the source of the drug, including the name and principal address of the seller;

b. the quantity of the drug, its dosage form and strength, date of purchase, sales invoice number, container size, number of containers and lot number;

c. the business name and address of each owner of the drug, and each owner's shipping information, including the address of the facility where each person certified delivery and receipt of the drug and the name of each person who made such certification;

d. a statement by the wholesale distributer that it has conducted due diligence of the wholesale distributor from which it purchased or may have purchased the drug; and

e. certification made under penalty of perjury, from the designated representative of the wholesale distributor that the information contained in the pedigree is true and accurate.

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

"Specified list of susceptible products" means a specific list of drugs or devices, to be determined by the commissioner, that are susceptible

to adulteration, counterfeiting or diversion and thereby pose a potential public health risk.

"USP" means the United States Pharmacopeia.

"Wholesale distribution" means the distribution of drugs or devices by a wholesale distributor to a person other than a consumer or patient and includes transfers of drugs from one pharmacy to another pharmacy if the value of the goods transferred exceeds 5% of total drug sales revenue of either the transferor or transferee pharmacy during any consecutive 12-month period. The term does not mean:

a. the sale, purchase, trade or dispensing of a drug or device pursuant to a prescription;

b. the transfer of a drug or device for emergency medical reasons such as transfers to alleviate a temporary shortage; sales to emergency medical services or licensed practitioners for use in the treatment of acutely ill or injured persons; and the provision of minimal emergency supplies of drugs to nearby nursing homes during hours when necessary drugs cannot be obtained;

c. intracompany transactions that do not violate own use provisions;

d. the sale, purchase or trade of a drug or device, or offer to sell, purchase or trade a drug or device among hospitals or other health care entities that are under common control or are members of the same group purchasing organization;

e. the sale, purchase or trade of a drug or device, or offer to sell, purchase or trade a drug or device 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;

f. the transfer of drugs or devices between pharmacies pursuant to a centralized prescription processing agreement; or

g. the distribution of drug samples by manufacturers' representatives or wholesale distributors' representatives.

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

6. (New section) a. A wholesale distributor engaged in the wholesale distribution of drugs or devices 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.

b. A wholesale distributor shall renew its license annually, and pay such license fees as established by the commissioner.

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, which shall not be identical to any name used by another wholesale distributor licensed in this State;

(2) the name, 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 name of the partnership and federal employer identification number;

(b) a corporation, the name, 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, 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; and

(3) the name, address and telephone number of each person who shall serve as the designated representative as provided in section 10 of P.L. , c. (C.)(pending before the Legislature as this bill).

d. An applicant shall obtain a surety bond of not less than $100,000, or other equivalent means of security, as determined by the commissioner, to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding the license. The department may make a claim against such bond or 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, including an appeal, before or on behalf of the department involving the wholesale distributor.

e. A licensed wholesale distributor located outside of this State who distributes drugs in this State shall 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 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.

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

the department.

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

7. (New section) The commissioner is authorized to require an applicant, designated representative and any person enumerated in subsection c. of section 6 of P.L. , c. (C.)(pending before the Legislature as this bill) to undergo a criminal history record background check for the purposes of determining eligibility for licensure, and to submit such information as is necessary to conduct the background check. The background check shall be conducted in compliance with applicable State and federal laws, at the applicant's expense, and include all states of residence since the applicant has been an adult. The commissioner is authorized to exchange fingerprint data with and receive criminal history record information from the State Bureau of Identification in the Division of State Police and the Federal Bureau of Investigation.

8. (New section) A manufacturer that is registered with the department shall establish and update on a monthly basis a list of its authorized distributors and authorized distributors of record. The list shall be filed with the department, which shall publish the list on its website.

9. (New section) a. The department shall determine eligibility for, and renewal of, licensure of persons engaged in the wholesale distribution of drugs and devices. 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 and applicant's eligibility:

(1) 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 or devices;

(2) The results of criminal history record background checks of: the applicant, designate representative and such other persons as specified in subsection c. of section 6 of P.L. , c. (C.)(pending before the Legislature as this bill) .

(3) The applicant's past experience in the manufacturing or distribution of drugs or devices;

(4) Whether the applicant furnished false or fraudulent material in any application related to drug or device manufacturing or distribution; and

(5) Compliance with previously granted licenses of any kind.

b. The applicant shall provide, and attest to, a statement disclosing any past criminal convictions and violations of state and federal laws regarding drugs or devices.

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

(1) Submit an application that includes the following information:

(a) his date and place of birth;

(b) occupations, positions of employment, and offices held during the past seven years, and the principal business addresses;

(c) whether he has been temporarily or permanently enjoined by a court of competent jurisdiction during the past seven years for violating any federal or state law regulating drugs or devices, together with details of such events;

(d) a description of any involvement with any business which manufactured, administered, prescribed, distributed or stored drugs or devices and which was named as a party in a lawsuit;

(e) a description of any criminal offense, excluding minor traffic violations, of which he, as an adult, was found or plead guilty. If the person indicates that a criminal conviction is under appeal, he shall submit a copy of the notice of appeal, and within 15 days after the disposition of the appeal, submit a copy of the final written order of disposition;

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

(g) the name, address, occupation, date and place of birth for each member of his immediate family. For purposes of this subsection, immediate family includes spouse, children, parents, siblings and the spouses of the children and siblings; and

(2) Have a minimum of two years of verifiable, full-time managerial or supervisory experience with a pharmacy or wholesale distributor licensed in this or another state, where responsibilities included record keeping, storage and shipment of drugs or devices;

(3) Serve as the designated representative for only one wholesale distributor at any one time;

(4) Be actively involved in and aware of the actual daily operations of the wholesale distributor. Active involvement means 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; and

(5) Complete continuing education programs specified by the commissioner regarding federal and State laws relevant to the distribution of drugs and devices.

b. Any additional personnel engaged in the operation and handling of drugs or devices shall possess the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

11. (New section) All facilities used for wholesale drug distribution

shall:

a. be of suitable construction to ensure that all drugs and devices in the facilities are maintained in accordance with labeling of such drugs and devices, or in compliance with 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 drugs and devices that are adulterated, counterfeit or suspected counterfeit, or otherwise unfit for distribution;

e. be maintained in a clean and orderly condition;

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

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

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

12. (New section) A wholesale distributor shall:

a. provide a pedigree for the wholesale distribution of drugs before the transaction to another wholesale distributor in accordance with the record keeping provisions of section 17 of P.L. , c. (C.) (pending before the Legislature as this bill);

b. 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. be duly registered with the federal Drug Enforcement Administration and the department; and

d. possess and maintain in good working order equipment that meets standards set by the commissioner and allows the wholesale distributor to authenticate, track and trace drugs or devices. The equipment shall be used to conduct for-cause and random tracking, tracing, and authentication of drugs or devices, pursuant to section 13 of P.L. , c. (C.) (pending before the Legislature as this bill).

13. (New section) a. (1) A wholesale distributor shall authenticate every distribution of a drug or device back to the manufacturer if he has reason to believe that any drug or device purchased from another wholesale distributor is adulterated, misbranded, counterfeit or suspected of being counterfeit, or otherwise unfit.

(2) A wholesale distributor who distributed a drug or device that

is the subject of an authentication pursuant to this section shall provide, upon request, information regarding the distribution of the drug or device, including: date of purchase; lot number; sales invoice number; contact information including name, address, telephone number and e-mail address, if available, for the wholesale distributor who sold the drug or device in question.

(3) If a wholesale distributor is unable to authenticate each transfer, he shall quarantine the drug or device and report this to the department and FDA within 10 business days after completing the attempted authentication.

(4) If the wholesale distributor satisfactorily completes the authentication, he shall maintain records of the authentication for three years, and produce them to the department and FDA upon request.

b. (1) A wholesale distributor who purchases drugs or devices from other wholesale distributors shall, at least annually, conduct random authentications of pedigrees on at least 10% of sales units of drugs or devices purchased from other wholesale distributors.

(2) A wholesale distributor shall, at least quarterly, conduct random authentications of pedigrees on at least 90% of sales units of drugs or devices purchased from other wholesale distributors if the drugs or devices are on the department's specified list of susceptible products.

(3) Wholesale distributors from whom other wholesale distributors have purchased drugs or devices shall cooperate with random authentications of pedigrees and provide requested information in a timely manner.

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

c. Upon receipt of a shipping container, a wholesale distributor shall review records for the acquisition of drugs or devices 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.

15. (New section) a. Any drug or device that was ordered in error or in excess of need by the wholesale distributor shall be returned to the manufacturer or wholesale distributor from which it was acquired, provided that three business days have not passed, the integrity of the

drug or device has been maintained and appropriate documentation is made to the pedigree.

b. Any drug or device, or any container or labeling that is outdated, damaged, deteriorated, misbranded, counterfeited, suspected of being counterfeited, adulterated, or otherwise deemed unfit for human consumption shall be quarantined until it is returned to the manufacturer or wholesale distributor from which it was acquired. Notice shall be provided to the department, FDA and manufacturer or wholesale distributor from which it was acquired within three business days.

c. Any drug or device that has been opened or used, but is not adulterated, misbranded, counterfeited, or suspected of being counterfeit, shall be so identified and quarantined until it is destroyed or returned to the manufacturer or wholesale distributor from which it was acquired.

d. If any condition under which a drug or device has been returned casts doubt on its safety, identity, strength, quality or purity, then the drug or device shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug or device meets appropriate standards of safety, identity, strength, quality and purity.

e. Contraband, counterfeit, or suspected counterfeit drugs and devices, evidence of criminal activity and accompanying documentation shall be retained until its disposition is authorized by the department and the FDA. 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 shall not be destroyed until its disposition is authorized by the department and FDA.

16. (New section) A wholesale distributor shall exercise due diligence in accordance with the following requirements, unless the commissioner waives any requirement:

a. Prior to the first purchase of drugs from another wholesale distributor, the purchasing wholesale distributor shall obtain the following information from the selling wholesale distributor:

(1) A list of states in which the wholesale distributor is licensed, and into which it ships drugs or devices ;

(2) Copies of all State and federal regulatory licenses and registrations;

(3) The wholesale distributor’s most recent facility inspection reports;

(4) Copies of relevant general and product liability insurance policies;

(5) A list of any other names under which the wholesale distributor does business or was formerly known;

(6) Names of corporate officers and managerial employees;

(7) Names of all persons who own more than 10% of the wholesale distributor, unless the wholesale distributor is publicly traded;

(8) A list of all disciplinary actions by state and federal agencies;

(9) A description, including the address, dimensions, and other relevant information, of each facility used for drug storage and distribution;

(10) A description of drug import and export activities of the wholesale distributor;

(11) A description of the wholesale distributor's process to comply with this act; and

(12) A statement whether and for whom the wholesale distributor is an authorized distributor of record.

b. Prior to the first purchase of drugs from another wholesale distributor, the purchasing wholesale distributor shall:

(1) verify the selling wholesale distributor's status as an authorized distributor of record, if applicable; and

(2) conduct, or engage a third party to conduct, an inspection of the wholesale distributor's facility if the facility has not been inspected by the department within three years of the contemplated purchase to ensure compliance with applicable laws and regulations relating to the storage and handling of drugs or devices.

c. At least annually, a wholesale distributor who purchases drugs from another wholesale distributor shall update the information required pursuant to section 17 of P.L. , c. (C.)(pending before the Legislature as this bill).

d. At least once every three years, a wholesale distributor who purchases drugs or devices from another wholesale distributor shall inspect, or engage a third party to inspect, the facility or facilities of the wholesale distributor from whom it is purchasing drugs as set forth in section 17 of P.L. , c. (C.) (pending before the Legislature as this bill), unless the facility has been inspected by the department within the last three years.

17. (New section) a. A wholesale distributor shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of drugs or devices. Such records shall include:

(1) If an authorized distributor, pedigrees for drugs distributed that are included on the department's list of susceptible products; or

(2) If not an authorized distributor, pedigrees for all drugs that are distributed.

b. Effective January 1, 2007, all wholesale distributors, whether located in or out-of-State, whether an authorized distributor or not, shall maintain an electronic pedigree in accordance with standards and requirements established by the department, for all drugs received and

distributed.

c. Records maintained pursuant to this section shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of the department. Records shall be made available for inspection for three years following their creation.

d. A wholesale distributor shall establish and maintain procedures for reporting to the department and FDA the existence of counterfeit or suspected counterfeit drugs or devices or counterfeiting or suspected counterfeiting activities, and significant shortages or losses of drugs or devices where diversion is known or suspected.

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

a. A procedure for handling recalls and withdrawals of drugs or devices;

b. A procedure to prepare for and protect against any crisis that affects security or operation of any facility;

c. A procedure for segregating, returning and destroying drugs and devices, and providing all necessary documentation;

d. A procedure for disposing and destruction of containers, labels, and packaging to ensure that they cannot be used in counterfeiting activities;

e. A procedure for investigating and reporting inventory discrepancies;

f. A procedure for timely reporting of criminal or suspected criminal activities to the department;

g. A procedure for conducting the for cause and random pedigree authentications in exercising due diligence required by section 16 of P.L. , c. (C.) (pending before the Legislature as this bill).

19. (New section) a. A person who engages in the wholesale distribution of drugs or devices and, with intent to defraud or deceive, fails to deliver to another person complete and accurate pedigree, when required, prior to transferring the drug or device to another person, is guilty of a crime of the third degree.

b. A person who engages in the wholesale distribution of drugs or devices, and with intent to defraud or deceive, fails to acquire complete and accurate pedigree, when required, concerning a drug or

device prior to obtaining the drug or device from another person, is guilty of a crime of the third degree.

c. A person who engages in the wholesale distribution of drugs or devices, and knowingly destroys, alters, conceals or fails to maintain complete and accurate pedigree concerning any drug or device in his possession, is guilty of a crime of the third degree.

d. A person who engages in the wholesale distribution of drugs or devices, who possesses pedigree documents required by the department, and knowingly fails to authenticate the matters contained in the documents as required, and nevertheless distributes or attempts to further distribute drugs or devices, is guilty of a crime of the third degree.

e. A person who engages in the wholesale distribution of drugs or devices, and with intent to defraud or deceive, falsely swears or certifies that he has authenticated any documents related to the wholesale distribution of drugs or devices, is guilty of a crime of the third degree.

f. A person who engages in the wholesale distribution of drugs or devices, and knowingly forges, counterfeits, or falsely creates any pedigree, who falsely represents any factual matter contained on any pedigree, or who knowingly omits to record material information required to be recorded in a pedigree, is guilty of a crime of the third degree.

g. A person who engages in the wholesale distribution of drugs or devices, and knowingly purchases or receives drugs or devices from a person not authorized to distribute drugs or devices in wholesale distribution, is guilty of a crime of the third degree.

h. A person who engages in the wholesale distribution of drugs or devices, and knowingly sells, barters, brokers, or transfers drugs or devices to a person not authorized to purchase drugs or devices, under the jurisdiction in which the person receives the drugs or devices in a wholesale distribution, is guilty of a crime of the third degree.

i. A person who knowingly possesses, actually or constructively, any amount of a contraband drug or device, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of a contraband drug or device, is guilty of a crime of the third degree.

j. A person who knowingly forges, counterfeits or falsely creates any label for a drug or device or who falsely represents any factual matter contained in any label of a drug or device is guilty of a crime of the third degree.

k. A person who knowingly manufactures, purchases, sells, delivers or brings into the State, or who is knowingly in actual or constructive possession of any amount of contraband drugs or devices, is guilty of a crime of the third degree.

l. 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 contraband drugs or devices, and whose acts result in the death of a person, is guilty of a crime of the first degree.

20. (New section) a. A court convicting and sentencing a defendant found guilty of a crime under section 19 of P.L. , c. (C.) (pending before the Legislature as this bill) shall order the defendant to forfeit to the State any real or personal property which was used or intended to be used to commit, facilitate or promote the commission of such crime or which constitutes, is derived from, or traceable to the gross proceeds that the defendant obtained directly or indirectly as a result of the crime.

b. Any property or assets subject to forfeiture under subsection a. of this section may be seized pursuant to a warrant obtained in the same manner as a search warrant or as otherwise permitted by law.

c. Monies ordered forfeited, or proceeds from the sale of other assets ordered forfeited shall be equitably divided between the department and other agencies involved in the investigation and prosecution which led to the conviction. Other property ordered forfeited after conviction of a defendant may, at the discretion of the investigating agencies, be placed into official use by the department or the agencies involved in the investigation and prosecution which led to the conviction.

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

22. This act shall take effect on the 180th day after enactment, except that the commissioner may take such anticipatory administrative action in advance as shall be necessary for the implementation of the act.

STATEMENT

The purpose of this bill is to promote the safety and effectiveness of prescription drugs and devices distributed in this State.

N.J.S.A.24:6B-1 et seq., which currently governs the licensure of both drug manufacturers and wholesale distributors, is amended in to eliminate references to wholesale distributors, and the balance of this bill establishes a separate, comprehensive scheme for regulating wholesale distributors.

The bill requires that wholesale distributors engaged in the

wholesale distribution of drugs and devices within this State, whether or not located within this State, be licensed by the Department of Health and Senior Services. The license would be renewed annually and the commissioner would determine reasonable fees for licensure and renewal.

An applicant for licensure would be required to undergo a criminal history record background check and to provide detailed information such as names, addresses, social security numbers, and dates of birth of owners, operators and key personnel, and depending on the legal form of the entity, other information about the principals involved in the entity. A surety bond of not less than $100,000, or other equivalent means of security, would be required to secure payment of any unpaid fees, costs or administrative penalties. The applicant's facility would undergo an inspection by the department prior to initial licensure, and periodically thereafter, at least once every three years.

The bill sets forth the minimum qualifications to be considered by the department in determining eligibility for licensure, but the Commissioner of Health and Senior Services may add any qualifications that he deems relevant to protecting the public health and safety. Factors to be considered in determining an applicant's eligibility include:

- suspension, sanction, or revocation of any license for violations of laws regarding drugs or devices;

- results of a criminal history record background checks;

- the applicant's past experience in the manufacture and distribution of drugs or devices;

- whether the applicant furnished false or fraudulent material in any application made in connection with drug or device manufacturing or distribution; and

- compliance with previously granted licenses of any kind.

The bill requires that a wholesale distributor designate a representative who is actively involved in and aware of its daily operations. The designated representative would be required to provide to the department detailed information, including:

- occupations, offices and positions of employment held during the past seven years;

- whether he has been temporarily or permanently enjoined by a court of competent jurisdiction during the past seven years for violating any federal or state law regulating drugs or devices;

- a description of any involvement during the previous seven years with any business which manufactured, distributed or stored drugs or devices and which was named as a party in a lawsuit;

- a description of any criminal offense, excluding minor traffic violations;

- a recent photograph of the person; and

- the name, address, occupation, date and place of birth for each

member of the person's family, including the person's spouse, children, parents, siblings, and the spouses of the person's children and siblings. The proposed designated representative would also be required to have a minimum of two years of verifiable, full-time managerial or supervisory experience with a pharmacy or wholesale distributor licensed in this State or another state. A designated representative would be permitted to serve only one wholesale distributor at a time, and would be required to complete continuing education programs specified by the commissioner.

All facilities used for wholesale drug distribution would have to meet standards of cleanliness, and be equipped with appropriate security systems that protect against theft, diversion and counterfeiting. The bill establishes minimum requirements for the proper storage, handling and shipment of drugs and devices, and mandates that records be maintained regarding these activities. The bill also requires that a wholesale distributor establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, transport and shipping and distribution of drugs.

A significant security and anti-counterfeiting measure in the bill is the pedigree requirement. "Pedigree" is defined as a document in written or electronic form that records each distribution of a drug or device, from the sale by a manufacturer though acquisition and sale by any wholesale distributor or repackager. A pedigree would include the following information with respect to each transaction:

- the quantity of the drug, its dosage form and strength, date of purchase, sales invoice number, container size, number of containers and lot number;

- the business name and address of each owner of the drug, and each owner's shipping information; and

- a statement by the wholesale distributer that it has conducted due diligence of the wholesale distributor from which it purchased or may have purchased the drug.

Effective January 1, 2007, all wholesale distributors will be required to establish and maintain an electronic pedigree system that meets the standards and requirements of the department.

The bill would require a wholesale distributor to possess and maintain in good working order technology and equipment that allows for authentication, and tracking and tracing of drugs or devices. The bill requires that two types of authentication be conducted: "for cause" authentication and "random" authentication. A wholesale distributor would be required to authenticate a drug or device back to the manufacturer if there is reason to believe that any drug or device purchased from another wholesale distributor is counterfeit, suspected of being counterfeit, misbranded or adulterated.

In addition, random authentications would be required at least annually on at least 10% of sales units of drugs or devices purchased

from other wholesale distributors. A wholesale distributor would also be required to conduct quarterly random authentications of pedigrees on at least 90% of sales units of drugs or devices purchased from other wholesale distributors that are on the department's specified list of susceptible products.

The bill also requires that a wholesale distributor visually examine each shipping container upon receipt to confirm its identity and determine if it may contain contaminated, contraband, counterfeit or damaged drugs or devices, or drugs or devices that are otherwise unfit for distribution. Any drugs or devices found to be unacceptable would be quarantined until further examination determines that the drugs or devices are fit. A drug or device whose container or label is adulterated, misbranded, counterfeited, or suspect of being counterfeit would be quarantined as well. Notice of any quarantine would be provided to the department, the FDA and the manufacturer or wholesale distributor from which it was acquired within three business days. Each outgoing shipment would be inspected to ensure that drugs or devices have not been damaged or held under improper conditions while in storage.

The bill also establishes due diligence requirements of wholesale distributors, which the commissioner is authorized to waive when appropriate. Due diligence requirements include investigating the following:

- a list of states the wholesale distributor is licensed in, and into which it ships drugs;

- copies of all State and federal regulatory licenses and registrations;

- the wholesale distributor's most recent facility inspection reports;

- information regarding general and product liability insurance, including copies of relevant policies;

- a list of other names under which the wholesale distributor is doing business, or was formerly known;

- a list of corporate officers and managerial employees;

- a list of all persons who own more than 10% of the wholesale distributor, unless the wholesale distributor is publicly traded;

- a list of all disciplinary actions by state and federal agencies;

- detailed information about each facility or warehouse used for drug storage and distribution;

- a description of drug import and export activities of the wholesale distributor;

- a description of the wholesale distributor's process to comply with this bill; and

- a statement as to whether and for whom the wholesale distributor is an authorized distributor of record.

The bill's extensive record-keeping provisions require that a wholesale distributor establish and maintain detailed records of all

transactions regarding the receipt, distribution or other disposition of drugs or devices. These records include pedigrees for drugs distributed that are included on the specified list of susceptible products if acquired from an authorized distributor, and if the acquisition is not from an authorized distributor, pedigrees for all drugs that are distributed.

Finally, the bill contains the following criminal provisions:

A person commits a crime of the third degree if he:

-engages in the wholesale distribution of drugs or devices and, with intent to defraud or deceive, fails to deliver to another person complete and accurate pedigree, when required, concerning a drug or device prior to transferring the drug or device to another person;

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

-engages in the wholesale distribution of drugs or devices and knowingly destroys, alters, conceals, or fails to maintain complete and accurate pedigree concerning any drug or device in his possession;

-engages in the wholesale distribution of drugs or devices and is in possession of drug pedigree documents required by the department and, knowingly fails to authenticate the matters contained in the documents as required and nevertheless distributes or attempts to further distribute drugs or devices;

-engages in the wholesale distribution of drugs or devices and, with intent to defraud or deceive, falsely swears or certifies that he has authenticated any documents related to the wholesale distribution of drugs or devices;

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

- engages in the wholesale distribution of drugs or devices and knowingly purchases or receives drugs or devices from a person not authorized to distribute drugs or devices in wholesale distribution;

- engages in the wholesale distribution of drugs or devices and knowingly sells, barters, brokers, or transfers drugs or devices to a person not authorized to purchase drugs or devices, under the jurisdiction in which the person receives the drugs or devices in a wholesale distribution;

- knowingly possesses, actually or constructively, any amount of contraband drugs or devices, and knowingly sells or delivers, or possesses with intent to sell or deliver, any amount of a contraband drug or device;

-knowingly forges, counterfeits, or falsely creates any label for a

drug or device, or falsely represents any factual matter contained in any label of a drug or device; or

-knowingly manufactures, purchases, sells, delivers or brings into the State, or is knowingly in actual or constructive possession of any amount of contraband drugs or devices;

A person commits a crime of the first degree if he knowingly manufactures, purchases, sells, delivers or brings into the State, or is knowingly in actual or constructive possession of any amount of contraband drugs or devices, and his acts result in the death of a person.

A person found guilty of any of the above offenses shall be ordered to forfeit to the State any real or personal property used or intended to be used to commit, facilitate or promote the commission of the offense, as well as property derived from, or traceable to the gross proceeds obtained directly or indirectly as a result of the offense. Forfeited monies or other assets ordered forfeited shall be equitably divided between the department and other agencies involved in the investigation and prosecution which led to the conviction.

ASSEMBLY HEALTH AND HUMAN SERVICES COMMITTEE

STATEMENT TO

ASSEMBLY COMMITTEE SUBSTITUTE FOR
ASSEMBLY, No. 3177

STATE OF NEW JERSEY

DATED: DECEMBER 6, 2004

The Assembly Health and Human Services Committee reports favorably an Assembly Committee Substitute for Assembly Bill No. 3177.

This committee substitute proposes to establish a new statute governing licensure of wholesale distributors of prescription drugs by the Department of Health and Senior Services (DHSS).

The substitute amends N.J.S.A.24:6B-1 et seq., which currently governs the licensure of both prescription drug manufacturers and wholesale distributors, to eliminate references to wholesale distributors, and establishes a separate, comprehensive scheme for regulating wholesale distributors.

Specifically, the substitute provides as follows:

C A wholesale distributor's license is to be renewed annually, and the Commissioner of Health and Senior Services is to determine reasonable fees for licensure and renewal.

-- An applicant for licensure is required to undergo a criminal history record background check and to provide detailed information such as names, addresses, Social Security numbers and dates of birth of owners, operators and key personnel, and other information about principals involved in the entity, depending on the legal form of the entity.

-- A surety bond or other equivalent means of security of at least $100,000 for businesses with over $10,000,000 in annual gross receipts and $25,000 for businesses with under $10,000,000 in annual gross receipts is to be required, although a separate surety bond is not to be required for each location or affiliated company, and the commissioner may waive the surety bond requirement at his discretion.

-- DHSS is to inspect the applicant's facility prior to initial licensure, and at least once every three years thereafter.

C The substitute sets forth the minimum qualifications for determining eligibility for licensure, but the commissioner may add any qualifications that the commissioner deems relevant to protecting the public health and safety. Factors to be considered in determining an applicant's eligibility include:

-- suspension, sanction or revocation of any license for violations

of laws regarding prescription drugs;

-- results of a criminal history record background check;

-- the applicant's past experience in the manufacture and distribution of prescription drugs;

-- whether the applicant furnished false or fraudulent material in any application made in connection with prescription drug manufacturing or distribution; and

-- compliance with previously granted licenses related to prescription drug distribution or health care services.

C A wholesale distributor is required to designate a representative who is actively involved in and aware of its daily operations.

-- The designated representative is required to provide detailed information to DHSS, including:

- occupations, offices and positions of employment held during the past seven years;

- whether the designated representative was temporarily or permanently enjoined by a court during the past seven years for violating any federal or state law regulating prescription drugs;

- a description of any involvement during the previous seven years with any business that manufactured, distributed or stored prescription drugs and was named as a party in a lawsuit;

- a description of any criminal offense, excluding minor traffic violations;

- a recent photograph of the person; and

- the name, address, occupation, date and place of birth for each member of the person's immediate family (including the person's spouse, children, parents and siblings, and the spouses of the person's children and siblings) who is employed by the wholesale distributor in a management or operations position or has ownership in the wholesale distribution business.

-- The proposed designated representative is also required to have at least two years of verifiable, full-time managerial or supervisory experience with a pharmacy or wholesale distributor licensed in this State or another state.

-- The designated representative would be permitted to serve only one wholesale distributor at a time.

C All facilities used for wholesale prescription drug distribution are required to meet standards of cleanliness and be equipped with appropriate security systems that protect against theft, diversion and counterfeiting.

-- The substitute establishes minimum requirements for the proper storage, handling and shipment of prescription drugs, and mandates that records be maintained regarding these activities.

-- A wholesale distributor is required to establish, maintain and adhere to written policies and procedures for the receipt, security, storage, inventory, transport, shipping and distribution of prescription drugs.

C The substitute includes a pedigree requirement as a significant

security and anti-counterfeiting measure. "Pedigree" is defined as a document in written or electronic form that records each distribution of a prescription drug, from the sale by a manufacturer though acquisition and sale by any wholesale distributor. A pedigree is to include the following information with respect to each transaction:

-- the quantity of the prescription drug, its dosage form and strength, date of purchase, sales invoice number, container size, number of containers and lot number;

-- the business name and address of each owner of the prescription drug, and each owner's shipping information; and

-- a statement by the wholesale distributer that it has conducted due diligence with respect to the wholesale distributor from which it purchased or may have purchased the prescription drug.

C Effective December 31, 2010, the commissioner is required to ensure that an electronic tracking system designed to deter and detect counterfeiting of prescription drugs is in place; and, by that date, all wholesale distributors will be required to possess and maintain in good working order technology and equipment that allows for authentication, tracking and tracing of prescription drugs.

C The substitute requires that two types of authentication of distributions of a prescription drug be conducted, "for cause" authentication and "random" authentication, as follows:

-- A wholesale distributor is required to authenticate a prescription drug back to the manufacturer if there is reason to believe that a prescription drug purchased from another wholesale distributor is counterfeit, suspected of being counterfeit, misbranded or adulterated.

-- Random authentications are required at least annually on at least 10% of sales units of prescription drugs purchased from other wholesale distributors. A wholesale distributor is also required to conduct quarterly random authentications of pedigrees on at least 90% of sales units of prescription drugs purchased from other wholesale distributors that are on the DHSS "specified list of susceptible products" established pursuant to the substitute.

C A wholesale distributor is required to visually examine each shipping container upon receipt to confirm its identity and determine if it may contain contaminated, contraband, counterfeit or damaged prescription drugs, or prescription drugs that are otherwise unfit.

-- A prescription drug found to be unacceptable is to be quarantined until further examination determines that it is fit; and a prescription drug whose container or label is adulterated, misbranded, counterfeit or suspected of being counterfeit is to be quarantined as well.

-- Notice of any quarantine is to be provided to DHSS, the federal Food and Drug Administration and the manufacturer or wholesale

distributor from which it was acquired within three business days.

C Each outgoing shipment is to be inspected to ensure that prescription drugs were not damaged or held under improper conditions while in storage.

C The substitute also establishes due diligence requirements for wholesale distributors, which the commissioner is authorized to waive when appropriate. Due diligence requirements include obtaining the following information from a selling wholesale distributor prior to the first purchase of prescription drugs from that distributor:

-- a list of states in which the wholesale distributor is domiciled, and into which it ships prescription drugs;

-- copies of all State and federal regulatory licenses and registrations to purchase, possess or distribute prescription drugs;

-- the wholesale distributor's most recent facility inspection reports;

-- information regarding general and product liability insurance, including copies of relevant policies;

-- a list of other names under which the wholesale distributor does or did business;

-- a list of corporate officers and managerial employees;

-- a list of all persons who own more than 10% of the wholesale distributor, unless the wholesale distributor is publicly traded;

-- a list of all disciplinary actions by state and federal agencies for the last seven years;

-- detailed information about each facility or warehouse used for prescription drug storage and distribution;

-- a description of prescription drug import and export activities of the wholesale distributor;

-- a description of the wholesale distributor's process to comply with this substitute; and

-- a statement as to whether and for whom the wholesale distributor is an authorized distributor of record.

C The substitute's extensive record-keeping provisions require that a wholesale distributor establish and maintain detailed records of all transactions regarding the receipt, distribution or other disposition of prescription drugs. These records include: pedigrees for prescription drugs distributed that are included on the specified list of susceptible products if acquired from an authorized distributor; and, if the acquisition is not from an authorized distributor, pedigrees for all prescription drugs that are distributed.

C The substitute contains the following criminal provisions:

-- A person commits a crime of the third degree if the person:

- 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, concerning a prescription drug prior to transferring the prescription drug to another

person;

- 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;

- 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;

- engages in the wholesale distribution of prescription drugs and is in possession of prescription drug pedigree documents required by DHSS, and knowingly fails to authenticate the matters contained in the documents as required and nevertheless distributes or attempts to further distribute prescription drugs;

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

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

- 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;

- 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;

- knowingly possesses, actually or constructively, any amount of contraband prescription drugs and knowingly sells or delivers, or possesses with intent to sell or deliver, any amount of a contraband prescription drug;

- 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

- knowingly manufactures, purchases, sells, delivers or brings into the State, or is knowingly in actual or constructive possession of, any amount of contraband prescription drugs.

-- A person commits a crime of the first degree if the person knowingly manufactures, purchases, sells, delivers or brings into the State, or is knowingly in actual or constructive possession of any amount of contraband prescription drugs, and those actions result in the death of a person.

-- A person who engages in the wholesale distribution of prescription drugs without having registered with DHSS as required

by this substitute is guilty of a misdemeanor.

- The substitute also provides for civil penalties for failure to comply with an order of the commissioner, ranging from $200 to $5,000 for the first offense, and from $1,000 to $20,000 for the second and subsequent offenses.
- A person found guilty of any of the above offenses is to be ordered to forfeit to the State any real or personal property used or intended to be used to commit, facilitate or promote the commission of the offense, as well as property derived from, or traceable to the gross proceeds obtained directly or indirectly as a result of, the offense. Forfeited monies or other assets ordered forfeited are to be equitably divided between DHSS and other agencies involved in the investigation and prosecution that led to the conviction.
- Finally, the substitute establishes a seven-member Wholesale Distribution Advisory Council in DHSS to consider proposed regulations on the distribution of prescription drugs and to recommend any practical measures that may improve the integrity of the prescription drug distribution system. The members are to include: the commissioner and the Director of the Division of Consumer Affairs in the Department of Law and Safety, or their designees; and representatives of wholesale distributors, prescription drug manufacturers and pharmacies.
- The substitute takes effect on the 180th day after enactment, but authorizes the commissioner to take anticipatory administrative action as necessary for its implementation.

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RELEASE: August 24, 2005

Codey Signs Bills Cracking Down on Illegal Sale, Use of Prescription and OTC Drugs

Bills will Regulate Wholesale Drug Distributors and Target Makers of "Crystal Meth"

(TRENTON) –Acting Governor Richard J. Codey today signed into law a package of bills designed to crack down on the booming black market of stolen prescription drugs and prevent certain over the counter drugs from being used to manufacture dangerous methamphetamines. The legislation was conceived in response to the largest pharmaceutical drug bust in state history, which took place in Bergen County in March 2004.

"People caught selling stolen or counterfeit prescription drugs should not receive a slap on the wrist. Their very actions threaten the public welfare while preying on innocent victims," said Codey. "A person pushing these drugs is no different than a crack-cocaine dealer when it comes to jeopardizing the public's health."

"By strengthening the regulation of wholesale drug distributors and increasing the penalties for illegal distribution and possession of prescription drugs, we are making sure that some of our most vulnerable citizens receive the life-saving medications they need – untainted," Codey said.

Codey signed the three bills during a public ceremony at HD Smith, a wholesale drug distributor in Carlstadt. He was joined by bill sponsors, including Senators Paul A. Sarlo (D-Bergen, Essex, Passaic) and Joseph M. Kyrillos (R-Middlesex, Monmouth) and Assembly members Frederick Scalera (D-Bergen, Essex, Passaic) and Linda Stender (D-Middlesex, Somerset, Union). Also in attendance were Health and Senior Services Commissioner Fred M. Jacobs, M.D., J.D. and Bergen County Prosecutor John Mollinelli.

The three bills are:
S1428, which upgrades the penalties for unlawful distribution and possession of prescription drugs from a disorderly persons offense to a third and fourth degree crime, respectively. The bill's sponsors include Senators Paul A. Sarlo (D-Bergen, Essex, Passaic), Joseph V. Doria, Jr. (D-Hudson) as well as Assembly members Frederick Scalera (D-Bergen, Essex, Passaic), Linda R. Greenstein (D-Mercer, Middlesex), Joseph Vas (D-Middlesex) and Neil M.Cohen (D-Union).

"Today we are saying that a drug dealer is a drug dealer. There is no difference between trafficking black market prescription drugs or trafficking illegal narcotics," said Sarlo. "I am proud to have sponsored this comprehensive legislation that will protect New Jersey's consumers, pharmacies and pharmaceutical industry from criminal elements."

S1753 establishes licensing requirements and standards for pharmaceutical wholesale distribution. The bill's sponsors include Senators Joseph F. Vitale (D-Middlesex) and Paul A. Sarlo (D-Bergen, Essex, Passaic).

"Today New Jersey is taking an important step in protecting New Jersey consumers from counterfeit and subpotent pharmaceuticals," said Vitale, Chair of the Senate Health, Human Services and Senior Citizens Committee. "For too long the federal government has delayed in enforcing its own laws in this area, so we are taking action to make sure that when someone picks up a prescription from the pharmacy, the medicine they get is safe and effective."

"This law will go a long way in protecting consumers from serious health and safety risks posed by counterfeit drugs. Increased fines and penalties and improved regulations for record-keeping, storage, transportation and distribution, demonstrate that New Jersey will not tolerate attempts to defraud and harm the public," said Dr. Jacobs.

S2320 restricts sales of ephedrine and pseudoephedrine and criminalizes certain possessions of anhydrous ammonia as precursors in the manufacturing of methamphetamine. The bill's sponsors include Senators Paul A. Sarlo (D-Bergen, Essex, Passaic), Joseph M. Kyrillos, Jr. (R-Middlesex, Monmouth) and Assembly members Linda Stender (D-Middlesex, Somerset, Union), Neil M. Cohen (D-Union) and Frederick Scalera (D-Bergen, Essex, Passaic).

Methamphetamine is a central nervous system stimulant like cocaine and caffeine. In the form of crystal meth, it can be produced relatively easily using ephedrine and pseudoephedrine as ingredients. Because these ingredients have many legitimate medical uses and are commonly sold over-the-counter as cold remedies, the new law is intended to make it more difficult to obtain the drugs for uses other than their legitimate medical purposes.

"Statistics indicate that states that have enacted legislation limiting the sale of products containing ephedrine and pseudoephedrine experienced a substantial decline in the number of meth labs. This bill is proactive as well as preventive legislation that will limit the potential inception of meth labs," said Scalera.

New Jersey now joins the growing list of more than 30 states that have imposed restrictions on the sale of products containing ephedrine and pseudoephedrine. New Jersey's legislation is part of a proactive measure to curb the spread of the methamphetamine epidemic, which is currently plaguing many mid-Western states and rural communities.