

24:6B-1

LEGISLATIVE HISTORY CHECKLIST

Compiled by the NJ State Law Library

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

VETO MESSAGE: No

[GOVERNOR'S PRESS RELEASE ON SIGNING:](#) [Yes](#)

FOLLOWING WERE PRINTED:

To check for circulating copies, contact New Jersey State Government Publications at the State Library (609) 278-2640 ext. 103 or <mailto:refdesk@njstatelib.org>

REPORTS:

No

HEARINGS:

No

NEWSPAPER ARTICLES:

Yes

See clippings for L.2005 c.205

IS 10/3/07

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

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

3

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

6

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

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

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

14

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

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

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

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

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

35 (d) The names and addresses of those individuals having actual
36 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 thus 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.

1 be the managing proprietor; partnership, the managing partners;
2 corporation, the officers and directors; or if any other type of
3 association, those having similar administrative responsibilities. (e) If
4 the business is to be conducted at more than one location in this State,
5 the name and address of the individual in charge of each such location.

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

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

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

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

15

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

18 12. (a) Any person who does not comply with an order of the
19 commissioner within the time specified shall be liable for the first
20 offense for a penalty, to be established by the commissioner of not
21 less than ~~[\$200.00]~~ \$200 nor more than ~~[\$2,000.00]~~ \$5,000 and for
22 the second and each succeeding offense for a penalty of not less than
23 ~~[\$1,000.00]~~ \$1,000 nor more than ~~[\$10,000.00]~~ \$20,000. The
24 penalties herein provided shall be enforced by the department as
25 plaintiff in a summary proceeding in accordance with ~~["the penalty~~
26 ~~enforcement law" (N.J.S.2A:58-1 et seq.)]~~ the "Penalty Enforcement
27 Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.).

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

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

33

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

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

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

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

42 (c) "Drugs" means "drugs" and "devices" as defined in ~~[section]~~
43 R.S. 24:1-1 [of the Revised Statutes].

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

46 (e) "Registrant" means the person in whose name a drug

1 manufacturing business or wholesale non-prescription drug business
2 is registered.

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

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

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

20

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

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

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

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

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

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

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

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

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

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

14 "Counterfeit prescription drug" means a prescription drug, or the
15 container, shipping container, seal or labeling thereof, which, without
16 authorization, bears the trademark, trade name or other identifying
17 mark, imprint, or any likeness thereof, of a manufacturer, processor,
18 packer or distributor other than the person or persons who in fact
19 manufactured, processed, packed or distributed such prescription drug
20 and which thereby falsely purports or is represented to be the product
21 of, or to have been packed or distributed by, such other manufacturer,
22 processor, packer or distributor.

23 "DEA" means the federal Drug Enforcement Administration.

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

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

31 "Distribute" means to sell, offer to sell, deliver, offer to deliver,
32 broker, give away or transfer a prescription drug, whether by passage
33 of title, physical movement, or both. The term does not mean to:
34 dispense or administer; deliver or offer to deliver in the usual course
35 of business as a common carrier ²or logistics provider²; or provide a
36 sample to a patient by a licensed practitioner, a health care
37 professional acting at the direction and under the supervision of a
38 practitioner, or the pharmacist of a health care facility licensed
39 pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) acting at the direction
40 of a practitioner.

41 "Drug" means: a. an article or substance recognized in the official
42 United States Pharmacopoeia, official Homeopathic Pharmacopoeia of
43 the United States or official National Formulary, or any supplement to
44 any of them; b. an article or substance intended for use in the
45 diagnosis, cure, mitigation, treatment or prevention of disease in man
46 or other animals; c. an article or substance, other than food, intended

1 to affect the structure of any function of the body of man or animals;
2 and d. an article or substance intended for use as a component of any
3 article or substance specified in clause a., b. or c.; but does not include
4 devices or their components, parts or accessories. Drug includes a
5 prefilled syringe or needle.

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

8 ²"Logistics provider" means an entity that receives drugs from the
9 original manufacturer and delivers them at the direction of that
10 manufacturer, and does not purchase, sell, trade or take title to the
11 drugs.²

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

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

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

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

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

42 "Specified list of susceptible products" means a specific list of
43 prescription drugs, to be determined by the commissioner, that are
44 considered to be potential targets for adulteration, counterfeiting or
45 diversion, which the commissioner shall provide to wholesale

1 distributors as prescription drugs are added to or removed from the
2 list, along with notification of those changes.

3 "Wholesale distribution" means the distribution of prescription
4 drugs in or into the State by a wholesale distributor to a person other
5 than a consumer or patient, and includes transfers of prescription
6 drugs from one pharmacy to another pharmacy if the value of the
7 goods transferred exceeds 5% of total prescription drug sales revenue
8 of either the transferor or transferee pharmacy during any consecutive
9 12-month period. The term excludes:

10 a. the sale, purchase or trade of a prescription drug, an offer to
11 sell, purchase, or trade a prescription drug, or the dispensing of a
12 prescription drug pursuant to a prescription;

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

16 c. the sale, purchase or trade of a prescription drug, or an offer to
17 sell, purchase or trade a prescription drug by ¹[pharmacy practice
18 sites] pharmacies¹, chain pharmacy distribution centers, and the
19 associated transfer of goods between chain pharmacy distribution
20 centers and their servicing wholesale distributors or manufacturers;

21 d. intracompany transactions or sales among wholesale
22 distributors, chain pharmacy distribution centers, and ¹[pharmacy
23 practice sites] pharmacies¹, and which are limited to those sales or
24 transfers of a prescription drug among members of an affiliated group,
25 even if the members of the affiliated group are separate legal
26 entities¹ [.] ¹;

27 e. the sale, purchase or trade of a prescription drug, or an offer to
28 sell, purchase or trade a prescription drug among hospitals or other
29 health care entities licensed pursuant to P.L.1971, c.136 (C.26:2H-1
30 et seq.) that are under common control;

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

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

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

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

- 1 j. the sale, purchase or trade of blood and blood components
2 intended for transfusion;
- 3 k. prescription drug returns, when conducted by a pharmacy, chain
4 pharmacy distribution center, hospital, health care entity licensed
5 pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) or charitable
6 institution in accordance with regulations established by the
7 commissioner;
- 8 l. the sale of minimal quantities of prescription drugs by retail
9 pharmacies to licensed practitioners for office use;
- 10 m. the stockpiling and distribution of drugs under the
11 authorization of a State agency for the purpose of providing those
12 products in an emergency situation; or
- 13 n. the sale, transfer, merger or consolidation of all or part of the
14 business of a pharmacy or pharmacies from or with another pharmacy
15 or pharmacies whether accomplished as a purchase and sale of stock
16 or business assets.
- 17 "Wholesale distributor" means any person, other than the
18 manufacturer, pharmacy ¹[practice site]¹, ²logistics provider,² or
19 chain pharmacy distribution center, engaged in wholesale distribution
20 of prescription drugs in or into the State and includes repackagers,
21 own-label distributors, private-label distributors, jobbers, brokers,
22 warehouses including distributors' warehouses, independent
23 prescription drug traders, and retail pharmacies that conduct wholesale
24 distribution.
- 25
- 26 6. (New section) a. A wholesale distributor engaged in the
27 wholesale distribution of prescription drugs within this State, whether
28 or not the wholesale distributor is located in this State, shall be
29 licensed by the department. If wholesale distribution operations are
30 conducted at more than one location, each such location shall be
31 licensed. The department may establish reciprocal agreements with
32 any state that has a drug wholesale licensure and standards program
33 that is at least as protective as the requirements set forth under this
34 act.
- 35 b. A wholesale distributor shall renew its license annually and pay
36 a license fee established by the commissioner. License fees shall be
37 used to support administrative and programmatic activities under this
38 act.
- 39 c. The commissioner shall establish the licensing and renewal form
40 and application process. An applicant shall provide the following
41 information, in addition to any other information that the
42 commissioner may require:
- 43 (1) all trade or business names, including current and former
44 fictitious business names used by the licensee, which names shall not
45 be identical to any name used by another unrelated wholesale

- 1 distributor licensed to purchase or sell prescription drugs in this State;
- 2 (2) the name, business address, Social Security number and date of
3 birth of each owner, partner or sole proprietor, as applicable, and each
4 operator, and
- 5 (a) if a partnership, the business name of the partnership and
6 federal employer identification number;
- 7 (b) if a corporation, the name, business address, Social Security
8 number, date of birth, and title of each corporate officer and director,
9 the corporate name including the name of any parent company, the
10 state of incorporation, federal employer identification number and
11 name, address and Social Security number of each shareholder owning
12 10% or more of voting stock;
- 13 (c) if a sole proprietorship, the federal employer identification
14 number; or
- 15 (d) if a limited liability company, the name of each member and
16 each manager, the company name and federal employer identification
17 number;
- 18 (3) the name, business address and telephone number of each
19 person who is serving as the designated representative pursuant to
20 section 10 of this act;
- 21 (4) a list of states in which the wholesale distributor is licensed to
22 purchase, possess and distribute prescription drugs, and into which it
23 ships prescription drugs;
- 24 (5) information regarding general and product liability insurance,
25 including certification of relevant coverage;
- 26 (6) a list of managerial employees;
- 27 (7) a list of all disciplinary actions by state and federal agencies
28 over the last four years;
- 29 (8) a description, including the address, dimensions, and other
30 relevant information, of each facility or warehouse used for
31 prescription drug storage and distribution;
- 32 (9) a description of prescription drug import and export activities
33 of the wholesale distributor;
- 34 (10) a description of the applicant's written procedures as required
35 under section 19 of this act; and
- 36 (11) if involved in the distribution of controlled dangerous
37 substances, evidence of registration with the department, as required
38 in section 2 of P.L.1970, c.226 (C.24:21-10), and evidence of
39 registration with the DEA.
- 40 d. (1) The commissioner shall require from an applicant a surety
41 bond of not less than \$100,000, or evidence of other equivalent means
42 of security acceptable to the department, such as insurance, an
43 irrevocable letter of credit or funds deposited in a trust account or
44 financial institution to secure payment of any administrative penalties
45 imposed by the department and any fees or costs incurred by the

1 department regarding that license when those penalties, fees or costs
2 are authorized under State law and the licensee fails to pay 30 days
3 after the penalty, fees or costs becomes final.

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

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

12 (4) The surety bond requirement may be waived, at the discretion
13 of the commissioner, if the wholesale distributor previously has
14 obtained a comparable surety bond or other equivalent means of
15 security for the purpose of licensure in another state where the
16 wholesale distributor possesses a valid license in good standing,
17 provided that a reciprocal agreement exists between this State and the
18 other state that extends authority to this State to make a claim against
19 the surety bond or other equivalent means of security.

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

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

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

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

45 h. The department shall make publicly available on its website the

1 dates of the first and most recent inspections of each wholesale
2 distributor.

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

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

9

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

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

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

38 b. The commissioner shall not license an applicant, designated
39 representative or any person enumerated in subsection c. of section 6
40 of this act if the criminal history record background information
41 reveals a disqualifying conviction. For the purposes of this section, a
42 disqualifying conviction shall mean a conviction of any of the
43 following crimes and offenses:

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

45 (a) involving danger to the person, meaning those crimes and

1 disorderly persons offenses set forth in N.J.S.2C:11-1 et seq.,
2 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
3 N.J.S.2C:15-1 et seq.; or

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

6 (c) involving health care claims fraud as set forth in P.L.1997,
7 c.353 (C.2C:21-4.2 et al.) or insurance fraud as set forth in sections
8 72 and 73 of P.L.2003, c.89 (C.2C:21-4.5 and 2C:21-4.6); or

9 (d) involving any controlled dangerous substance or controlled
10 substance analog as set forth in chapter 35 of Title 2C of the New
11 Jersey Statutes except paragraph (4) of subsection a. of N.J.S.2C:35-
12 10; or

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

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

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

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

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

39 e. Notwithstanding the provisions of subsection b. of this section
40 to the contrary, the commissioner may offer provisional licensure for
41 a period not to exceed three months if the applicant, designated
42 representative or person enumerated in subsection c. of section 6 of
43 this act submits to the commissioner a sworn statement attesting that
44 the person has not been convicted of any disqualifying conviction
45 pursuant to this section, and the commissioner determines that no

1 criminal history record background information exists on file in the
2 Division of State Police or the Federal Bureau of Investigation which
3 would disqualify the person.

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

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

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

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

18 (4) the date of the crime or offense;

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

21 (6) whether the crime or offense was an isolated or repeated
22 incident;

23 (7) any social conditions which may have contributed to the
24 commission of the crime or offense; and

25 (8) any evidence of rehabilitation, including good conduct in prison
26 or in the community, counseling or psychiatric treatment received,
27 acquisition of additional academic or vocational schooling, successful
28 participation in correctional work-release programs, or the
29 recommendation of those who have had the individual under their
30 supervision.

31

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

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

46 (1) 5,000 sales units per company within 12 months; or

1 (2) 12 purchases by invoice at the manufacturer's minimum
2 purchasing requirement per invoice within 12 months.

3
4 9. (New section) The department shall determine eligibility for
5 licensure and renewal thereof, of persons engaged in the wholesale
6 distribution of prescription drugs. In addition to any additional factors
7 that the commissioner may deem relevant to protecting the public
8 health and safety, the following shall be considered in determining an
9 applicant's eligibility:

10 a. any suspension, sanction or revocation by a federal, state or
11 local government of any license currently or previously held by the
12 applicant or any of its owners for violations of laws regarding drugs;

13 b. the results of the applicant's criminal history record background
14 check pursuant to section 7 of this act and information regarding the
15 applicant's business provided pursuant to section 6 of this act;

16 c. the applicant's past experience in the manufacturing or
17 distribution of drugs;

18 d. whether the applicant furnished false or fraudulent material in
19 any application related to drug manufacturing or distribution;

20 e. compliance with previously granted licenses related to drug
21 distribution or any health care professional or occupational licenses;
22 and

23 f. a driver's license and Social Security number verification for all
24 company officers, key management, principals and owners, provided
25 that the review does not conflict with State confidentiality laws.

26
27 10. (New section) In addition to satisfying any requirements that
28 the commissioner may establish by regulation, a designated
29 representative shall:

30 a. submit an application that includes the following information:

31 (1) the person's date and place of birth;

32 (2) the person's occupations, positions of employment and offices
33 held during the past seven years, and the principal business addresses;

34 (3) whether the person has been temporarily or permanently
35 enjoined by a court of competent jurisdiction during the past four
36 years for violating any federal or state law regulating drugs, along with
37 the details of those events;

38 (4) a description of any involvement by the person with any
39 business that manufactured, administered, prescribed, distributed or
40 stored prescription drugs and was named as a party in a lawsuit;

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

42 (6) the name, business address, occupation, date and place of birth
43 for each member of the person's immediate family who is employed by
44 the wholesale distributor in a management or operations position or
45 has ownership in the wholesale distribution business. As used in this
46 paragraph, the term "member of the person's immediate family"

- 1 includes the person's spouse, children, parents and siblings, and the
2 spouses of the person's children and the person's siblings; and
3 (7) such other information as the commissioner deems relevant.
- 4 b. have a minimum of two years of verifiable, full-time managerial,
5 supervisory, auditing or compliance experience with: (1) a pharmacy,
6 wholesale distributor or drug manufacturer licensed, permitted or
7 registered in this or another state, territory of the United States or the
8 District of Columbia; (2) a nationally recognized drug trade
9 association; or (3) a state or federal agency, where the person's
10 responsibilities included record keeping, storage and shipment of
11 prescription drugs;
- 12 c. serve as the designated representative for only one wholesale
13 distributor location at any one time; and
- 14 d. be actively involved in and aware of the actual daily operations
15 of the wholesale distributor. As used in this subsection, "actively
16 involved" means being: employed full-time in a managerial position;
17 physically present at the facility during normal business hours; and
18 knowledgeable about all policies and procedures pertaining to the
19 wholesale distributor's operations. A designated representative may
20 seek assistance from qualified individuals to help ensure compliance
21 with the provisions of this subsection.
- 22
- 23 11. (New section) All facilities used for wholesale prescription
24 drug distribution shall:
- 25 a. be of suitable construction to ensure that all prescription drugs
26 in the facilities are maintained in accordance with their labeling or
27 official compendium standards;
- 28 b. be of suitable size and construction to facilitate cleaning,
29 maintenance and proper wholesale distribution operations;
- 30 c. have adequate storage, lighting, ventilation, temperature,
31 sanitation, humidity, space, equipment and security conditions;
- 32 d. have a quarantine area for prescription drugs that are
33 adulterated, counterfeit or suspected of being counterfeit, or otherwise
34 unfit for distribution;
- 35 e. be maintained in a clean and orderly condition and free from
36 infestation;
- 37 f. be secure from unauthorized entry, with the outside perimeter
38 of the premises well-lighted and entry into areas where prescription
39 drugs are held limited to authorized personnel;
- 40 g. be equipped with security and inventory management and
41 control systems that provide suitable protection against theft, diversion
42 or counterfeiting, and can readily provide data to the department; and
- 43 h. be a commercial location and not a personal dwelling or
44 residence.

1 12. (New section) a. Before the sale or return of a prescription
2 drug to another wholesale distributor, a selling wholesale distributor
3 shall provide a pedigree or a certification in accordance with the
4 following specifications:

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

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

12 b. A wholesale distributor shall provide for the secure and
13 confidential storage of information with restricted access and policies
14 and procedures to protect the integrity and confidentiality of the
15 information.

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

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

21
22 13. (New section) The commissioner shall report annually to the
23 Legislature on the availability of an effective standardized electronic
24 product identification tracking system for prescription drugs in this
25 State. The report shall address whether such a system can be feasibly
26 implemented by manufacturers, wholesale distributors and pharmacies
27 for purposes of authentication, and deterrence and detection of
28 counterfeit drugs. If the commissioner determines that implementation
29 of such a system is feasible, he shall make recommendations regarding
30 the timing and method of implementing the system.

31
32 14. (New section) a. (1) A wholesale distributor shall authenticate
33 every distribution of a prescription drug back to the manufacturer if
34 the wholesale distributor has reason to believe that a prescription drug
35 purchased from another wholesale distributor is adulterated,
36 misbranded or counterfeit.

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

44 (3) If a wholesale distributor is unable to authenticate each
45 transfer, the wholesale distributor shall quarantine the prescription

1 drug and report this to the department within 14 days after completing
2 the attempted authentication.

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

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

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

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

17

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

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

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

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

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

37

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

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

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

1 pharmacy and wholesale distributor;

2 (c) has been maintained in its original packaging;

3 (d) has had its integrity maintained; and

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

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

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

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

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

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

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

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

36 h. A wholesale distributor:

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

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

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

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

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

15 c. the wholesale distributor's most recent facility inspection
16 reports;

17 d. copies of relevant general and product liability insurance
18 coverage;

19 e. a list of any other names under which the wholesale distributor
20 does business or was formerly known;

21 f. names of corporate officers and managerial employees;

22 g. a list of all disciplinary actions by state and federal agencies
23 involving wholesale distribution of drugs for the last four years, if the
24 selling wholesale distributor supplies it upon request by the purchasing
25 wholesale distributor; and

26 h. a description, including the address, dimensions and other
27 relevant information, of each facility used for prescription drug storage
28 and distribution.

29
30 18. (New section) a. A person who receives or passes a pedigree
31 or certification pursuant to this act shall maintain the document or
32 record for three years from receipt or passing of the document or
33 record.

34 b. A wholesale distributor shall:

35 (1) establish and maintain records of all transactions regarding the
36 receipt, distribution or other disposition of all prescription drugs,
37 including the dates of receipt and distribution or other disposition of
38 the prescription drugs; and

39 (2) make its inventories and other records available for inspection
40 and copying by an authorized official of any local, State or federal
41 governmental agency for a period of three years following the creation
42 of those records.

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

45 (1) if kept at the inspection site or immediately retrievable by

1 computer or other electronic means, are readily available for
2 authorized inspection during the retention period; and

3 (2) if kept at a central location apart from the inspection site and
4 not electronically retrievable, are made available for inspection within
5 two business days of a request by an authorized official of any State
6 or federal governmental agency charged with enforcement of the
7 provisions of this act.

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

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

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

18

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

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

28 (1) for handling recalls and withdrawals of prescription drugs;

29 (2) to prepare for and protect against any crisis that affects the
30 security or operation of any facility;

31 (3) for segregating, returning and destroying prescription drugs,
32 and providing all necessary documentation;

33 (4) for disposal and destruction of containers, labels and packaging
34 to ensure that they cannot be used in counterfeiting activities, which
35 procedures shall require retention of all necessary documentation for
36 at least three years, and appropriate witnessing of the destruction of
37 any labels, packaging, immediate containers or containers in
38 accordance with federal and State requirements;

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

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

1 (7) for satisfying authentication requirements required by section
2 14 of this act.

3

4 20. (New section) a. A person is guilty of a crime of the third
5 degree if the person:

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

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

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

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

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

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

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

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

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

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

1 in any label of a prescription drug; or

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

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

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

13

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

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

28

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

35

36 23. (New section) a. There is created a Wholesale Drug
37 Distribution Advisory Council within the department to advise the
38 department regarding proposed rules on the distribution of
39 prescription drugs and to recommend any practical measures that may
40 improve the integrity of the prescription drug distribution system.

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

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

45 (2) three persons employed by different wholesale distributors

1 licensed in this State, one of whom shall be appointed by the
2 Governor, one by the President of the Senate and one by the Speaker
3 of the General Assembly;

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

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

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

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

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

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

25
26 24. (New section) In accordance with the "Administrative
27 Procedure Act," P.L.1968, c.410 (C.152:14B-1 et seq.), the
28 commissioner shall adopt rules and regulations to ensure the safety and
29 sanitary conduct of pharmaceutical distribution and to carry out the
30 provisions of this act.

31
32 25. This act shall take effect on the 180th day after enactment,
33 except that the Commissioner of Health and Senior Services may take
34 such anticipatory administrative action in advance as shall be necessary
35 for the implementation of the act.

36 _____
37
38 Establishes licensing requirements and standards for pharmaceutical
39 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:

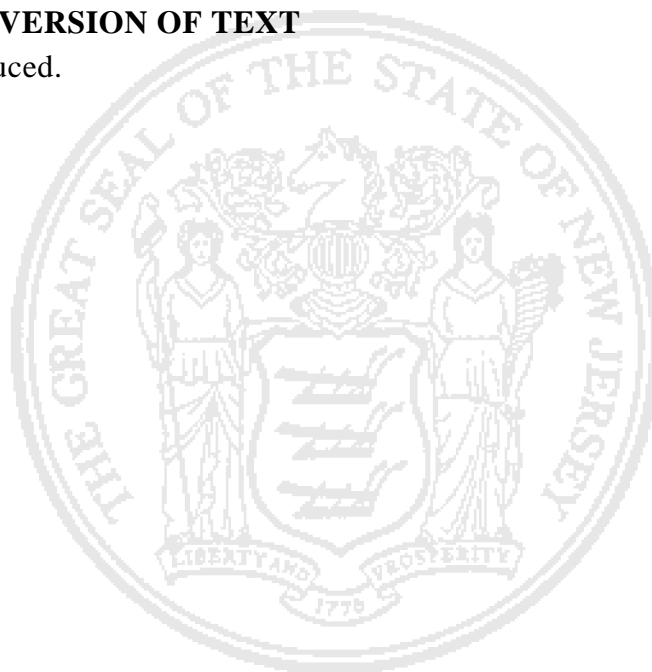
Senator Buono

SYNOPSIS

Establishes licensing requirements and standards for pharmaceutical wholesale distribution.

CURRENT VERSION OF TEXT

As introduced.



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

S1753 VITALE, SARLO

2

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

3

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

6

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

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

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

14

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

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

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

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

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

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

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

43 (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 thus is new matter.

1 manufactured for sale [or wholesaled].

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

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

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

9

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

12 12. (a) Any person who does not comply with an order of the
13 commissioner within the time specified shall be liable for the first
14 offense for a penalty, to be established by the commissioner of not
15 less than \$200.00 nor more than \$2,000.00 and for the second and
16 each succeeding offense for a penalty of not less than \$1,000.00 nor
17 more than \$10,000.00. The penalties herein provided shall be
18 enforced by the department as plaintiff in a summary proceeding in
19 accordance with ["the penalty enforcement law" (N.J.S. 2A:58-1 et
20 seq.)] the "Penalty Enforcement Law of 1999," P.L.1999, c.274
21 (C.2A:58-10 et seq.).

22 (b) Any person, who engages or continues to engage in the
23 manufacturing [or wholesaling] of drugs without having registered
24 with the department as required by this act is guilty of a misdemeanor.
25 (cf: P.L.1983, c.275, s.6)

26

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

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

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

33 (b) "Department" means the [State] Department of Health and
34 Senior Services.

35 (c) "Drugs" means "drugs" and "devices" as defined in section
36 24:1-1 of the Revised Statutes.

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

39 (e) "Registrant" means the person in whose name a drug
40 manufacturing business [or wholesale drug business] is registered.

41 (f) "Drug manufacturing business" means the business of creating,
42 making or producing drugs by compounding, growing or other
43 process. This definition shall apply to persons engaged in the drug
44 manufacturing business who do not maintain a manufacturing location
45 in this State but do operate distribution depots or warehouses of such

1 business in this State. This definition shall not apply to licensed
2 pharmacies or to licensed professional individuals such as, but not
3 limited to, pharmacists, physicians, dentists, or veterinarians when
4 engaged in the lawful pursuit of their professions.

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

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

13

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

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

23 "Authenticate" means to affirmatively verify before any distribution
24 of a drug or device that each transaction listed on the pedigree, if a
25 pedigree is required, and other accompanying documentation has
26 occurred.

27 "Authorized distributor" or "authorized distributor of record"
28 means a wholesale distributor with whom a manufacturer has
29 established an ongoing relationship to distribute the manufacturer's
30 products. An ongoing relationship is deemed to exist when the
31 wholesale distributor:

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

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

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

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

44 "Counterfeit" with respect to a drug or device means a drug or
45 device, or the container, shipping container, seal or labeling thereof,
46 which, without authorization, bears the trademark, trade name or other

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

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

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

11 a. to dispense or administer;

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

14 c. to provide a sample to a patient by a licensed practitioner, a
15 health care professional acting at the direction and under the
16 supervision of a practitioner, or the pharmacist of a health care facility
17 acting at the direction of such a practitioner.

18 "FDA" means the federal Food and Drug Administration.

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

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

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

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

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

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

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

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

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

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

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

3 "USP" means the United States Pharmacopeia.

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

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

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

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

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

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

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

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

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

38

39 6. (New section) a. A wholesale distributor engaged in the
40 wholesale distribution of drugs or devices within this State, whether
41 or not the wholesale distributor is located in this State, shall be
42 licensed by the department. If wholesale distribution operations are
43 conducted at more than one location, each such location shall be
44 licensed.

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

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

5 (1) all trade or business names, which shall not be identical to any
6 name used by another wholesale distributor licensed in this State;

7 (2) the name, address, social security number and date of birth of
8 each owner, partner or sole proprietor, as applicable, and each
9 operator, and

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

12 (b) if a corporation, the name, address, social security number, date
13 of birth, and title of each corporate officer and director, the corporate
14 name including the name of any parent company, the state of
15 incorporation, federal employer identification number and name,
16 address and social security number of each shareholder owning 10%
17 or more of voting stock;

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

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

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

26 d. An applicant shall obtain a surety bond of not less than
27 \$100,000, or other equivalent means of security, as determined by the
28 commissioner, to secure payment of any administrative penalties
29 imposed by the department and any fees and costs incurred by the
30 department regarding the license. The department may make a claim
31 against such bond or security until one year after the wholesale
32 distributor's license ceases to be valid or until 60 days after the
33 conclusion of any administrative or legal proceeding, including an
34 appeal, before or on behalf of the department involving the wholesale
35 distributor.

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

41 f. Each wholesale distribution facility shall undergo an inspection
42 by the department prior to initial licensure and at least once every
43 three years thereafter, in accordance with a schedule to be determined
44 by the commissioner.

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

1 the department.

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

4

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

18

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

24

25 9. (New section) a. The department shall determine eligibility for,
26 and renewal of, licensure of persons engaged in the wholesale
27 distribution of drugs and devices. In addition to any additional factors
28 that the commissioner may deem relevant to protecting the public
29 health and safety, the following shall be considered in determining and
30 applicant's eligibility:

31 (1) Any suspension, sanction, or revocation by a federal, state, or
32 local government of any license currently or previously held by the
33 applicant or any of its owners for violations of laws regarding drugs
34 or devices;

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

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

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

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

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

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

3

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

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

8 (a) his date and place of birth;

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

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

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

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

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

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

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

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

36 (4) Be actively involved in and aware of the actual daily operations
37 of the wholesale distributor. Active involvement means employed full-
38 time in a managerial position, physically present at the facility during
39 normal business hours and knowledgeable about all policies and
40 procedures pertaining to the wholesale distributor's operations; and

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

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

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

3
4 11. (New section) All facilities used for wholesale drug distribution
5 shall:

6 a. be of suitable construction to ensure that all drugs and devices
7 in the facilities are maintained in accordance with labeling of such
8 drugs and devices, or in compliance with official compendium
9 standards;

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

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

14 d. have a quarantine area for drugs and devices that are
15 adulterated, counterfeit or suspected counterfeit, or otherwise unfit for
16 distribution;

17 e. be maintained in a clean and orderly condition;

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

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

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

27

28 12. (New section) A wholesale distributor shall:

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

33 b. provide for the secure and confidential storage of information
34 with restricted access and policies and procedures to protect the
35 integrity and confidentiality of the information;

36 c. be duly registered with the federal Drug Enforcement
37 Administration and the department; and

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

44

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

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

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

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

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

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

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

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

30

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

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

41 c. Upon receipt of a shipping container, a wholesale distributor
42 shall review records for the acquisition of drugs or devices for
43 accuracy and completeness.

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

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

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

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

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

26 e. Contraband, counterfeit, or suspected counterfeit drugs and
27 devices, evidence of criminal activity and accompanying
28 documentation shall be retained until its disposition is authorized by
29 the department and the FDA. The shipping container, immediate or
30 sealed outer or secondary container or labeling, and accompanying
31 documentation, which is suspected of or determined to be counterfeit
32 or fraudulent shall not be destroyed until its disposition is authorized
33 by the department and FDA.

34
35 16. (New section) A wholesale distributor shall exercise due
36 diligence in accordance with the following requirements, unless the
37 commissioner waives any requirement:

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

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

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

45 (3) The wholesale distributor's most recent facility inspection
46 reports;

- 1 (4) Copies of relevant general and product liability insurance
- 2 policies;
- 3 (5) A list of any other names under which the wholesale distributor
- 4 does business or was formerly known;
- 5 (6) Names of corporate officers and managerial employees;
- 6 (7) Names of all persons who own more than 10% of the wholesale
- 7 distributor, unless the wholesale distributor is publicly traded;
- 8 (8) A list of all disciplinary actions by state and federal agencies;
- 9 (9) A description, including the address, dimensions, and other
- 10 relevant information, of each facility used for drug storage and
- 11 distribution;
- 12 (10) A description of drug import and export activities of the
- 13 wholesale distributor;
- 14 (11) A description of the wholesale distributor's process to comply
- 15 with this act; and
- 16 (12) A statement whether and for whom the wholesale distributor
- 17 is an authorized distributor of record.
- 18 b. Prior to the first purchase of drugs from another wholesale
- 19 distributor, the purchasing wholesale distributor shall:
- 20 (1) verify the selling wholesale distributor's status as an authorized
- 21 distributor of record, if applicable; and
- 22 (2) conduct, or engage a third party to conduct, an inspection of the
- 23 wholesale distributor's facility if the facility has not been inspected by
- 24 the department within three years of the contemplated purchase to
- 25 ensure compliance with applicable laws and regulations relating to the
- 26 storage and handling of drugs or devices.
- 27 c. At least annually, a wholesale distributor who purchases drugs
- 28 from another wholesale distributor shall update the information
- 29 required pursuant to section 17 of P.L. , c. (C.)(pending before the
- 30 Legislature as this bill).
- 31 d. At least once every three years, a wholesale distributor who
- 32 purchases drugs or devices from another wholesale distributor shall
- 33 inspect, or engage a third party to inspect, the facility or facilities of
- 34 the wholesale distributor from whom it is purchasing drugs as set forth
- 35 in section 17 of P.L. , c. (C.) (pending before the Legislature as this
- 36 bill), unless the facility has been inspected by the department within
- 37 the last three years.
- 38
- 39 17. (New section) a. A wholesale distributor shall establish and
- 40 maintain records of all transactions regarding the receipt and
- 41 distribution or other disposition of drugs or devices. Such records
- 42 shall include:
- 43 (1) If an authorized distributor, pedigrees for drugs distributed that
- 44 are included on the department's list of susceptible products; or
- 45 (2) If not an authorized distributor, pedigrees for all drugs that are
- 46 distributed.

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

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

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

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

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

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

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

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

35 e. A procedure for investigating and reporting inventory
36 discrepancies;

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

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

42
43 19. (New section) a. A person who engages in the wholesale
44 distribution of drugs or devices and, with intent to defraud or deceive,
45 fails to deliver to another person complete and accurate pedigree,
46 when required, prior to transferring the drug or device to another

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

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

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

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

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

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

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

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

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

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

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

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

3 1. A person who knowingly manufactures, purchases, sells, delivers,
4 or brings into the State, or is knowingly in actual or constructive
5 possession of any amount of contraband drugs or devices, and whose
6 acts result in the death of a person, is guilty of a crime of the first
7 degree.

8
9 20. (New section) a. A court convicting and sentencing a
10 defendant found guilty of a crime under section 19 of P.L. , c. (C.)
11 (pending before the Legislature as this bill) shall order the defendant
12 to forfeit to the State any real or personal property which was used or
13 intended to be used to commit, facilitate or promote the commission
14 of such crime or which constitutes, is derived from, or traceable to the
15 gross proceeds that the defendant obtained directly or indirectly as a
16 result of the crime.

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

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

28
29 21. In accordance with the "Administrative Procedure Act,"
30 P.L.1968, c.410 (C.52:14B-1 et seq.), the commissioner shall
31 promulgate rules and regulations to ensure the safety and sanitary
32 conduct of pharmaceutical distribution and to carry out the provisions
33 of this act.

34
35 22. This act shall take effect on the 180th day after enactment,
36 except that the commissioner may take such anticipatory
37 administrative action in advance as shall be necessary for the
38 implementation of the act.

39

40

41

STATEMENT

42

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

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

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

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

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

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

- 26 - suspension, sanction, or revocation of any license for violations
27 of laws regarding drugs or devices;
- 28 - results of a criminal history record background checks;
- 29 - the applicant's past experience in the manufacture and distribution
30 of drugs or devices;
- 31 - whether the applicant furnished false or fraudulent material in any
32 application made in connection with drug or device manufacturing or
33 distribution; and
- 34 - compliance with previously granted licenses of any kind.

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

- 39 - occupations, offices and positions of employment held during the
40 past seven years;
- 41 - whether he has been temporarily or permanently enjoined by a
42 court of competent jurisdiction during the past seven years for
43 violating any federal or state law regulating drugs or devices;
- 44 - a description of any involvement during the previous seven years
45 with any business which manufactured, distributed or stored drugs or
46 devices and which was named as a party in a lawsuit;

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

3 - a recent photograph of the person; and

4 - the name, address, occupation, date and place of birth for each
5 member of the person's family, including the person's spouse, children,
6 parents, siblings, and the spouses of the person's children and siblings.
7 The proposed designated representative would also be required to
8 have a minimum of two years of verifiable, full-time managerial or
9 supervisory experience with a pharmacy or wholesale distributor
10 licensed in this State or another state. A designated representative
11 would be permitted to serve only one wholesale distributor at a time,
12 and would be required to complete continuing education programs
13 specified by the commissioner.

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

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

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

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

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

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

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

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

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

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

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

- 28 - a list of states the wholesale distributor is licensed in, and into
29 which it ships drugs;
- 30 - copies of all State and federal regulatory licenses and
31 registrations;
- 32 - the wholesale distributor's most recent facility inspection reports;
- 33 - information regarding general and product liability insurance,
34 including copies of relevant policies;
- 35 - a list of other names under which the wholesale distributor is
36 doing business, or was formerly known;
- 37 - a list of corporate officers and managerial employees;
- 38 - a list of all persons who own more than 10% of the wholesale
39 distributor, unless the wholesale distributor is publicly traded;
- 40 - a list of all disciplinary actions by state and federal agencies;
- 41 - detailed information about each facility or warehouse used for
42 drug storage and distribution;
- 43 - a description of drug import and export activities of the wholesale
44 distributor;
- 45 - a description of the wholesale distributor's process to comply with
46 this bill; and

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

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

11 Finally, the bill contains the following criminal provisions:

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

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

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

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

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

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

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

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

41 - engages in the wholesale distribution of drugs or devices and
42 knowingly sells, barter, brokers, or transfers drugs or devices to a
43 person not authorized to purchase drugs or devices, under the
44 jurisdiction in which the person receives the drugs or devices in a
45 wholesale distribution;

46 - knowingly possesses, actually or constructively, any amount of

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

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

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

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

15 A person found guilty of any of the above offenses shall be ordered
16 to forfeit to the State any real or personal property used or intended
17 to be used to commit, facilitate or promote the commission of the
18 offense, as well as property derived from, or traceable to the gross
19 proceeds obtained directly or indirectly as a result of the offense.
20 Forfeited monies or other assets ordered forfeited shall be equitably
21 divided between the department and other agencies involved in the
22 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:

- C 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.
- C 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.
- C 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.
- C 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.
- C All facilities used for wholesale prescription drug distribution are required to meet standards of cleanliness and be equipped with appropriate security systems.

- C 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.
- C 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.
- C 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.
- C 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.
- 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. A wholesale distributor shall also ensure that each outgoing shipment of prescription drugs was not damaged or held under improper conditions while in storage.
- C A manufacturer or wholesale distributor who receives returned prescriptions is required to notify DHSS of the return.
- C 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.

- C 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.
- C 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.
- C 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.
- C A person found guilty of any of the above offenses may be ordered to forfeit to the State any real or personal property.
- C 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.
- C 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:

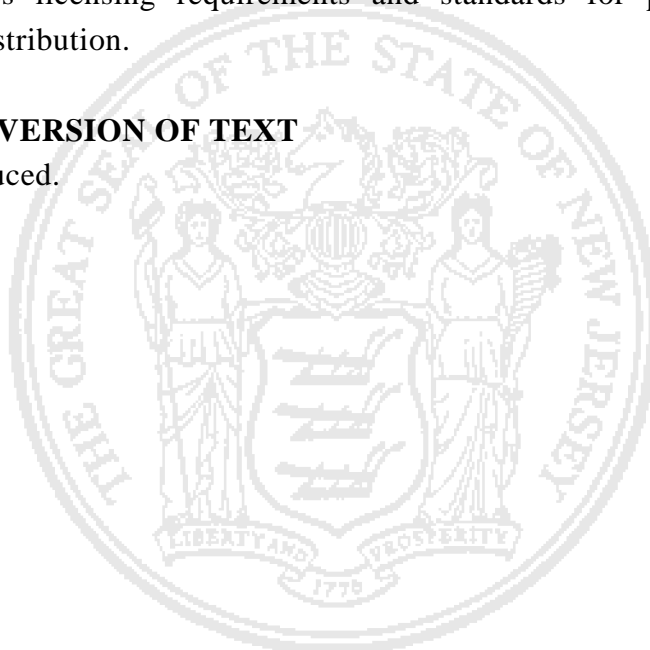
Assemblywoman Voss

SYNOPSIS

Establishes licensing requirements and standards for pharmaceutical wholesale distribution.

CURRENT VERSION OF TEXT

As introduced.



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

A3177 SCALERA, GREENSTEIN

2

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

3

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

6

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

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

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

14

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

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

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

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

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

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

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

43 (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 thus is new matter.

1 manufactured for sale [or wholesaled].

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

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

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

9

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

12 12. (a) Any person who does not comply with an order of the
13 commissioner within the time specified shall be liable for the first
14 offense for a penalty, to be established by the commissioner of not
15 less than \$200.00 nor more than \$2,000.00 and for the second and
16 each succeeding offense for a penalty of not less than \$1,000.00 nor
17 more than \$10,000.00. The penalties herein provided shall be
18 enforced by the department as plaintiff in a summary proceeding in
19 accordance with ["the penalty enforcement law" (N.J.S.2A:58-1 et
20 seq.)] the "Penalty Enforcement Law of 1999," P.L.1999, c.274
21 (C.2A:58-10 et seq.).

22 (b) Any person, who engages or continues to engage in the
23 manufacturing [or wholesaling] of drugs without having registered
24 with the department as required by this act is guilty of a misdemeanor.
25 (cf: P.L.1983, c.275, s.6)

26

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

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

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

33 (b) "Department" means the [State] Department of Health and
34 Senior Services.

35 (c) "Drugs" means "drugs" and "devices" as defined in section
36 24:1-1 of the Revised Statutes.

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

39 (e) "Registrant" means the person in whose name a drug
40 manufacturing business [or wholesale drug business] is registered.

41 (f) "Drug manufacturing business" means the business of creating,
42 making or producing drugs by compounding, growing or other
43 process. This definition shall apply to persons engaged in the drug
44 manufacturing business who do not maintain a manufacturing location
45 in this State but do operate distribution depots or warehouses of such

1 business in this State. This definition shall not apply to licensed
2 pharmacies or to licensed professional individuals such as, but not
3 limited to, pharmacists, physicians, dentists, or veterinarians when
4 engaged in the lawful pursuit of their professions.

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

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

13
14 5. (New section) As used in sections 5 through 7 and 9 through 20
15 of P.L. , c. (C.) (pending before the Legislature as this bill):

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

23 "Authenticate" means to affirmatively verify before any distribution
24 of a drug or device that each transaction listed on the pedigree, if a
25 pedigree is required, and other accompanying documentation has
26 occurred.

27 "Authorized distributor" or "authorized distributor of record"
28 means a wholesale distributor with whom a manufacturer has
29 established an ongoing relationship to distribute the manufacturer's
30 products. An ongoing relationship is deemed to exist when the
31 wholesale distributor:

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

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

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

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

44 "Counterfeit" with respect to a drug or device means a drug or
45 device, or the container, shipping container, seal or labeling thereof,
46 which, without authorization, bears the trademark, trade name or other

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

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

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

11 a. to dispense or administer;

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

14 c. to provide a sample to a patient by a licensed practitioner, a
15 health care professional acting at the direction and under the
16 supervision of a practitioner, or the pharmacist of a health care facility
17 acting at the direction of such a practitioner.

18 "FDA" means the federal Food and Drug Administration.

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

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

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

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

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

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

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

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

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

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

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

3 "USP" means the United States Pharmacopeia.

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

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

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

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

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

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

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

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

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

38

39 6. (New section) a. A wholesale distributor engaged in the
40 wholesale distribution of drugs or devices within this State, whether
41 or not the wholesale distributor is located in this State, shall be
42 licensed by the department. If wholesale distribution operations are
43 conducted at more than one location, each such location shall be
44 licensed.

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

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

5 (1) all trade or business names, which shall not be identical to any
6 name used by another wholesale distributor licensed in this State;

7 (2) the name, address, social security number and date of birth of
8 each owner, partner or sole proprietor, as applicable, and each
9 operator, and

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

12 (b) a corporation, the name, address, social security number, date
13 of birth, and title of each corporate officer and director, the corporate
14 name including the name of any parent company, the state of
15 incorporation, federal employer identification number and name,
16 address and social security number of each shareholder owning 10%
17 or more of voting stock;

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

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

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

26 d. An applicant shall obtain a surety bond of not less than
27 \$100,000, or other equivalent means of security, as determined by the
28 commissioner, to secure payment of any administrative penalties
29 imposed by the department and any fees and costs incurred by the
30 department regarding the license. The department may make a claim
31 against such bond or security until one year after the wholesale
32 distributor's license ceases to be valid or until 60 days after the
33 conclusion of any administrative or legal proceeding, including an
34 appeal, before or on behalf of the department involving the wholesale
35 distributor.

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

41 f. Each wholesale distribution facility shall undergo an inspection
42 by the department prior to initial licensure and at least once every
43 three years thereafter, in accordance with a schedule to be determined
44 by the commissioner.

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

1 the department.

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

4

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

18

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

24

25 9. (New section) a. The department shall determine eligibility for,
26 and renewal of, licensure of persons engaged in the wholesale
27 distribution of drugs and devices. In addition to any additional factors
28 that the commissioner may deem relevant to protecting the public
29 health and safety, the following shall be considered in determining and
30 applicant's eligibility:

31 (1) Any suspension, sanction, or revocation by a federal, state, or
32 local government of any license currently or previously held by the
33 applicant or any of its owners for violations of laws regarding drugs
34 or devices;

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

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

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

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

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

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

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

5 (a) his date and place of birth;

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

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

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

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

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

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

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

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

33 (4) Be actively involved in and aware of the actual daily operations
34 of the wholesale distributor. Active involvement means employed full-
35 time in a managerial position, physically present at the facility during
36 normal business hours and knowledgeable about all policies and
37 procedures pertaining to the wholesale distributor's operations; and

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

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

45
46 11. (New section) All facilities used for wholesale drug distribution

1 shall:

2 a. be of suitable construction to ensure that all drugs and devices
3 in the facilities are maintained in accordance with labeling of such
4 drugs and devices, or in compliance with official compendium
5 standards;

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

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

10 d. have a quarantine area for drugs and devices that are
11 adulterated, counterfeit or suspected counterfeit, or otherwise unfit for
12 distribution;

13 e. be maintained in a clean and orderly condition;

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

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

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

23

24 12. (New section) A wholesale distributor shall:

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

29 b. provide for the secure and confidential storage of information
30 with restricted access and policies and procedures to protect the
31 integrity and confidentiality of the information;

32 c. be duly registered with the federal Drug Enforcement
33 Administration and the department; and

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

40

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

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

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

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

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

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

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

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

26

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

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

37 c. Upon receipt of a shipping container, a wholesale distributor
38 shall review records for the acquisition of drugs or devices for
39 accuracy and completeness.

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

42

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

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

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

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

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

22 e. Contraband, counterfeit, or suspected counterfeit drugs and
23 devices, evidence of criminal activity and accompanying
24 documentation shall be retained until its disposition is authorized by
25 the department and the FDA. The shipping container, immediate or
26 sealed outer or secondary container or labeling, and accompanying
27 documentation, which is suspected of or determined to be counterfeit
28 or fraudulent shall not be destroyed until its disposition is authorized
29 by the department and FDA.

30

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

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

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

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

41 (3) The wholesale distributor's most recent facility inspection
42 reports;

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

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

- 1 (6) Names of corporate officers and managerial employees;
- 2 (7) Names of all persons who own more than 10% of the wholesale
3 distributor, unless the wholesale distributor is publicly traded;
- 4 (8) A list of all disciplinary actions by state and federal agencies;
- 5 (9) A description, including the address, dimensions, and other
6 relevant information, of each facility used for drug storage and
7 distribution;
- 8 (10) A description of drug import and export activities of the
9 wholesale distributor;
- 10 (11) A description of the wholesale distributor's process to comply
11 with this act; and
- 12 (12) A statement whether and for whom the wholesale distributor
13 is an authorized distributor of record.
- 14 b. Prior to the first purchase of drugs from another wholesale
15 distributor, the purchasing wholesale distributor shall:
 - 16 (1) verify the selling wholesale distributor's status as an authorized
17 distributor of record, if applicable; and
 - 18 (2) conduct, or engage a third party to conduct, an inspection of
19 the wholesale distributor's facility if the facility has not been inspected
20 by the department within three years of the contemplated purchase to
21 ensure compliance with applicable laws and regulations relating to the
22 storage and handling of drugs or devices.
- 23 c. At least annually, a wholesale distributor who purchases drugs
24 from another wholesale distributor shall update the information
25 required pursuant to section 17 of P.L. , c. (C.) (pending before
26 the Legislature as this bill).
- 27 d. At least once every three years, a wholesale distributor who
28 purchases drugs or devices from another wholesale distributor shall
29 inspect, or engage a third party to inspect, the facility or facilities of
30 the wholesale distributor from whom it is purchasing drugs as set forth
31 in section 17 of P.L. , c. (C.) (pending before the Legislature as
32 this bill), unless the facility has been inspected by the department
33 within the last three years.
- 34
- 35 17. (New section) a. A wholesale distributor shall establish and
36 maintain records of all transactions regarding the receipt and
37 distribution or other disposition of drugs or devices. Such records
38 shall include:
 - 39 (1) If an authorized distributor, pedigrees for drugs distributed that
40 are included on the department's list of susceptible products; or
 - 41 (2) If not an authorized distributor, pedigrees for all drugs that are
42 distributed.
- 43 b. Effective January 1, 2007, all wholesale distributors, whether
44 located in or out-of-State, whether an authorized distributor or not,
45 shall maintain an electronic pedigree in accordance with standards and
46 requirements established by the department, for all drugs received and

1 distributed.

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

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

14

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

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

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

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

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

31 e. A procedure for investigating and reporting inventory
32 discrepancies;

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

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

38

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

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

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

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

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

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

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

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

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

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

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

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

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

1 possession of any amount of contraband drugs or devices, and whose
2 acts result in the death of a person, is guilty of a crime of the first
3 degree.

4
5 20. (New section) a. A court convicting and sentencing a
6 defendant found guilty of a crime under section 19 of P.L. , c. (C.)
7 (pending before the Legislature as this bill) shall order the defendant
8 to forfeit to the State any real or personal property which was used or
9 intended to be used to commit, facilitate or promote the commission
10 of such crime or which constitutes, is derived from, or traceable to the
11 gross proceeds that the defendant obtained directly or indirectly as a
12 result of the crime.

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

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

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

30
31 22. This act shall take effect on the 180th day after enactment,
32 except that the commissioner may take such anticipatory
33 administrative action in advance as shall be necessary for the
34 implementation of the act.

35
36
37 STATEMENT

38
39 The purpose of this bill is to promote the safety and effectiveness
40 of prescription drugs and devices distributed in this State.

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

46 The bill requires that wholesale distributors engaged in the

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

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

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

- 22 - suspension, sanction, or revocation of any license for violations
23 of laws regarding drugs or devices;
- 24 - results of a criminal history record background checks;
- 25 - the applicant's past experience in the manufacture and distribution
26 of drugs or devices;
- 27 - whether the applicant furnished false or fraudulent material in any
28 application made in connection with drug or device manufacturing or
29 distribution; and
- 30 - compliance with previously granted licenses of any kind.

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

- 35 - occupations, offices and positions of employment held during the
36 past seven years;
- 37 - whether he has been temporarily or permanently enjoined by a
38 court of competent jurisdiction during the past seven years for
39 violating any federal or state law regulating drugs or devices;
- 40 - a description of any involvement during the previous seven years
41 with any business which manufactured, distributed or stored drugs or
42 devices and which was named as a party in a lawsuit;
- 43 - a description of any criminal offense, excluding minor traffic
44 violations;
- 45 - a recent photograph of the person; and
- 46 - the name, address, occupation, date and place of birth for each

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

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

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

- 25 - the quantity of the drug, its dosage form and strength, date of
26 purchase, sales invoice number, container size, number of containers
27 and lot number;
- 28 - the business name and address of each owner of the drug, and
29 each owner's shipping information; and
- 30 - a statement by the wholesale distributor that it has conducted due
31 diligence of the wholesale distributor from which it purchased or may
32 have purchased the drug.

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

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

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

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

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

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

- 24 - a list of states the wholesale distributor is licensed in, and into
25 which it ships drugs;
- 26 - copies of all State and federal regulatory licenses and
27 registrations;
- 28 - the wholesale distributor's most recent facility inspection reports;
- 29 - information regarding general and product liability insurance,
30 including copies of relevant policies;
- 31 - a list of other names under which the wholesale distributor is
32 doing business, or was formerly known;
- 33 - a list of corporate officers and managerial employees;
- 34 - a list of all persons who own more than 10% of the wholesale
35 distributor, unless the wholesale distributor is publicly traded;
- 36 - a list of all disciplinary actions by state and federal agencies;
- 37 - detailed information about each facility or warehouse used for
38 drug storage and distribution;
- 39 - a description of drug import and export activities of the wholesale
40 distributor;
- 41 - a description of the wholesale distributor's process to comply with
42 this bill; and
- 43 - a statement as to whether and for whom the wholesale distributor
44 is an authorized distributor of record.

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

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

7 Finally, the bill contains the following criminal provisions:

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

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

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

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

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

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

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

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

37 - engages in the wholesale distribution of drugs or devices and
38 knowingly sells, barter, brokers, or transfers drugs or devices to a
39 person not authorized to purchase drugs or devices, under the
40 jurisdiction in which the person receives the drugs or devices in a
41 wholesale distribution;

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

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

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

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

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

11 A person found guilty of any of the above offenses shall be ordered
12 to forfeit to the State any real or personal property used or intended
13 to be used to commit, facilitate or promote the commission of the
14 offense, as well as property derived from, or traceable to the gross
15 proceeds obtained directly or indirectly as a result of the offense.
16 Forfeited monies or other assets ordered forfeited shall be equitably
17 divided between the department and other agencies involved in the
18 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 through 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 distributor 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, barter, brokers or transfers prescription drugs to a person not authorized to purchase prescription drugs under the jurisdiction in which the person receives the prescription drugs in a wholesale distribution;

- 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.

- C 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.
- C 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.
- C 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.
- C The substitute takes effect on the 180th day after enactment, but authorizes the commissioner to take anticipatory administrative action as necessary for its implementation.

PO BOX 004
TRENTON, NJ 08625

Contact: Kelley Heck
609-777-2600

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.