

[Second Reprint]

SENATE COMMITTEE SUBSTITUTE FOR
SENATE, No. 1753

STATE OF NEW JERSEY
211th LEGISLATURE

ADOPTED FEBRUARY 7, 2005

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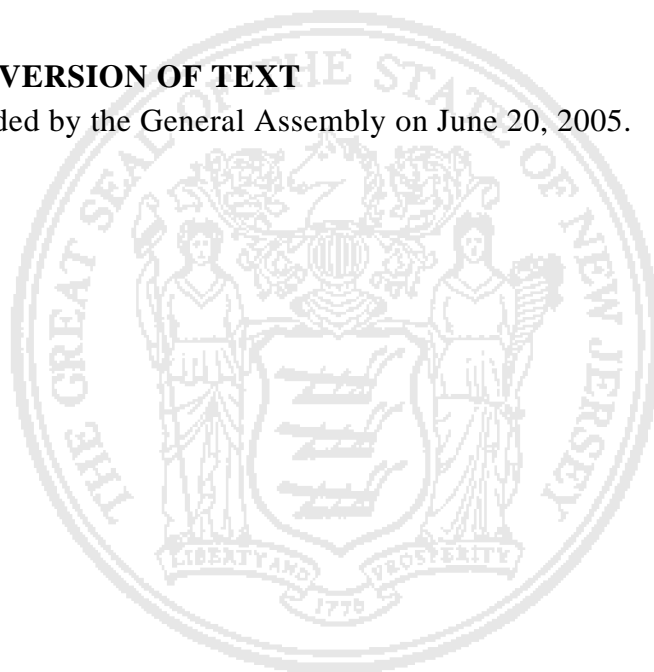
Senator Buono

SYNOPSIS

Establishes licensing requirements and standards for pharmaceutical wholesale distribution.

CURRENT VERSION OF TEXT

As amended by the General Assembly on June 20, 2005.



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
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.

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

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

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

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

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

13
14 3. Section 12 of P.L.1961, c.52 (C.24:6B-11) is amended to read
15 as follows:

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

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

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

31
32 4. Section 13 of P.L.1961, c. 52 (C.24:6B-12) is amended to read
33 as follows:

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

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

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

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

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

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

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

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

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

18
19 5. (New section) As used in sections 5 through 24 of P.L. , c.
20 (C.) (pending before the Legislature as this bill):

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

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

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

- 36 a. 5,000 sales units per company within 12 months; or
37 b. 12 purchases by invoice at the manufacturer's minimum
38 purchasing requirement per invoice within 12 months.

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

44 "Chain pharmacy distribution center" means a distribution facility
45 or warehouse owned by and operated for the primary use of a group

1 of pharmacies that are under common or affiliated control or
2 ownership.

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

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

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

21 "DEA" means the federal Drug Enforcement Administration.

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

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

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

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

1 article or substance specified in clause a., b. or c.; but does not include
2 devices or their components, parts or accessories. Drug includes a
3 prefilled syringe or needle.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 "Wholesale distributor" means any person, other than the
16 manufacturer, pharmacy ¹[practice site]¹, ²logistics provider,² or
17 chain pharmacy distribution center, engaged in wholesale distribution
18 of prescription drugs in or into the State and includes repackagers,
19 own-label distributors, private-label distributors, jobbers, brokers,
20 warehouses including distributors' warehouses, independent
21 prescription drug traders, and retail pharmacies that conduct wholesale
22 distribution.

23
24 6. (New section) a. A wholesale distributor engaged in the
25 wholesale distribution of prescription drugs within this State, whether
26 or not the wholesale distributor is located in this State, shall be
27 licensed by the department. If wholesale distribution operations are
28 conducted at more than one location, each such location shall be
29 licensed. The department may establish reciprocal agreements with
30 any state that has a drug wholesale licensure and standards program
31 that is at least as protective as the requirements set forth under this
32 act.

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

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

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

45 (2) the name, business address, Social Security number and date of

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

1 after the penalty, fees or costs becomes final.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

43 (a) involving danger to the person, meaning those crimes and
44 disorderly persons offenses set forth in N.J.S.2C:11-1 et seq.,
45 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

1 N.J.S.2C:15-1 et seq.; or

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

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

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

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

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

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

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

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

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

1 would disqualify the person.

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

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

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

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

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

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

19 (6) whether the crime or offense was an isolated or repeated
20 incident;

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

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

29

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

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

44 (1) 5,000 sales units per company within 12 months; or

45 (2) 12 purchases by invoice at the manufacturer's minimum
46 purchasing requirement per invoice within 12 months.

1

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

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

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

14 c. the applicant's past experience in the manufacturing or
15 distribution of drugs;

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

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

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

24

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

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

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

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

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

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

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

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

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

1 shall provide a pedigree or a certification in accordance with the
2 following specifications:

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

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

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

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

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

19

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

29

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

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

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

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

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

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

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

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

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

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

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

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

35
36 16. (New section) a. (1) A pharmacy, chain pharmacy distribution
37 center or pharmacy member of an affiliated group shall return to a
38 wholesale distributor any prescription drug that is on the specified list
39 of susceptible products if the prescription drug:

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

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

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

1 (d) has had its integrity maintained; and
2 (e) is accompanied by appropriate and complete documentation
3 and, where applicable, any necessary notations made to the
4 certification, invoice or packing slip.

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

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

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

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

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

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

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

34 h. A wholesale distributor:

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

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

43

44 17. (New section) A wholesale distributor shall exercise due
45 diligence in accordance with the following requirements, unless the

1 commissioner waives any requirement. Prior to the first purchase of
2 prescription drugs for distribution in this State from another wholesale
3 distributor that is not licensed in this State pursuant to this act, the
4 purchasing wholesale distributor shall obtain the following information
5 from the selling wholesale distributor:

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

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

13 c. the wholesale distributor's most recent facility inspection
14 reports;

15 d. copies of relevant general and product liability insurance
16 coverage;

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

19 f. names of corporate officers and managerial employees;

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

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

27

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

32 b. A wholesale distributor shall:

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

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

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

43 (1) if kept at the inspection site or immediately retrievable by
44 computer or other electronic means, are readily available for
45 authorized inspection during the retention period; and

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

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

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

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

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

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

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

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

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

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

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

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

44 (7) for satisfying authentication requirements required by section
45 14 of this act.

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

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

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

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

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

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

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

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

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

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

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

(11) knowingly manufactures, purchases, sells, delivers or brings

1 into the State, or is knowingly in actual or constructive possession of
2 any amount of a contraband prescription drug.

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

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

11

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

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

26

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

33

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

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

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

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

1 of the General Assembly;

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

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

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

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

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

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

23

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

29

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