24:21-54

LEGISLATIVE HISTORY CHECKLIST

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LAWS OF: 2007 **CHAPTER:** 244

NJSA: 24:21-54 (Establishes Prescription Monitoring Program in Division of Consumer Affairs and provides division with authority over registration and control of controlled dangerous substances)

BILL NO: S1604 (Substituted for A1624)

SPONSOR(S) Rice and Others

DATE INTRODUCED: March 6, 2006

COMMITTEE: **ASSEMBLY:** Appropriations

SENATE: Budget and Appropriations; Health, Human Services and Senior Citizens

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: **ASSEMBLY:** December 13, 2007

SENATE: December 17, 2007

DATE OF APPROVAL: January 4, 2008

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (Senate Committee Substitute Third reprint enacted)

S1604

SPONSOR'S STATEMENT: (Begins on page 5 of original bill) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: Yes

SENATE: Yes Health 12-14-06
Budget 1-29-07

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, ***may possibly*** be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT: Yes

LEGISLATIVE FISCAL ESTIMATE: Yes

A1624

SPONSOR'S STATEMENT: (Begins on page 5 of original bill) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: Yes Health 1-18-07
Approp. 6-14-07

SENATE: No

FLOOR AMENDMENT STATEMENT: Yes

LEGISLATIVE FISCAL ESTIMATE: Yes

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GOVERNOR'S PRESS RELEASE ON SIGNING: No

FOLLOWING WERE PRINTED:

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REPORTS: No

HEARINGS: No

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RWH 5/29/08

§23 - C.24:21-54
& Note to
§§24-32
§§24-32 -
C.45:1-44 to
45:1-52
§33 - Repealer
§34 - Note to
§§1-33

P.L. 2007, CHAPTER 244, ***approved January 4, 2008***
Senate Committee Substitute ***(Third Reprint)*** for
Senate, No. 1604

AN ACT concerning controlled dangerous substances, amending P.L.1970, c.226, P.L.1971, c.3 and P.L.2003, c.280, supplementing Titles 24 and 45 of the Revised Statutes, and repealing section 41 of P.L.1970, c.226.

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

1. Section 2 of P.L.1970, c.226 (C.24:21-2) is amended to read as follows:

2. Definitions. As used in this act:

"Administer" means the direct application of a controlled dangerous substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by: (1) a practitioner (or, in his presence, by his lawfully authorized agent), or (2) the patient or research subject at the lawful direction and in the presence of the practitioner.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser but does not include a common or contract carrier, public warehouseman, or employee thereof.

["Bureau of Narcotics and Dangerous Drugs" means the Bureau of Narcotics and Dangerous Drugs, United States Department of Justice.**]**

"Commissioner" means the **[**State**]** Commissioner of Health <u>and Senior Services</u>.

"Controlled dangerous substance" means a drug, substance, or immediate precursor in Schedules I through V of article 2 of **[**this act**]** <u>P.L.1970, c.226 (C.24:21-1 et seq.), as amended and supplemented</u>. The term shall not include distilled spirits, wine, malt beverages, as those terms are defined or used in R.S.33:1-1 et seq., or tobacco and tobacco products.

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

Matter underlined <u>thus</u> is new matter.
Matter enclosed in superscript numerals has been adopted as follows:
[1] Senate SBA committee amendments adopted January 29, 2007.
[2] Senate floor amendments adopted February 22, 2007.
[3] Assembly AAP committee amendments adopted June 14, 2007.

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

"Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a controlled dangerous substance, whether or not there is an agency relationship.

"Director" means the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

"Dispense" means to deliver a controlled dangerous substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. "Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled dangerous substance. "Distributor" means a person who distributes.

"Division" means the Division of Consumer Affairs in the Department of Law and Public Safety.

"Drug Enforcement Administration" means the Drug Enforcement Administration in the United States Department of Justice.

"Drugs" means (a) substances recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (b) substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (c) substances (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) substances intended for use as a component of any article specified in subsections (a), (b) and (c) of this section; but does not include devices or their components, parts or accessories.

"Drug dependent person" means a person who is using a controlled dangerous substance and who is in a state of psychic or physical dependence, or both, arising from the use of that controlled dangerous substance on a continuous basis. Drug dependence is characterized by behavioral and other responses, including but not limited to a strong compulsion to take the substance on a recurring basis in order to experience its psychic effects, or to avoid the discomfort of its absence. "Hashish" means the resin extracted

from any part of the plant Genus Cannabis L. and any compound, manufacture, salt, derivative, mixture, or preparation of such resin.

"Marihuana" means all parts of the plant Genus Cannabis L. , whether growing or not; the seeds thereof; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds, except those containing resin extracted from such plant; but shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks, fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

"Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled dangerous substance, either directly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a controlled dangerous substance by an individual for his own use or the preparation, compounding, packaging, or labeling of a controlled dangerous substance: (1) by a practitioner as an incident to his administering or dispensing of a controlled dangerous substance in the course of his professional practice, or (2) by a practitioner (or under his supervision) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(a) Opium, coca leaves, and opiates;

(b) A compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates;

(c) A substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in subsections (a) and (b), except that the words "narcotic drug" as used in this act shall not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.

"Official written order" means an order written on a form provided for that purpose by the Attorney General of the United States or his delegate, under any laws of the United States making provisions therefor, if such order forms are authorized and required by the federal law, and if no such form is provided, then on an official form provided for that purpose by the **[**State Department of Health**]** <u>division. If authorized by the Attorney General of the</u>

United States or the division, the term shall also include an order transmitted by electronic means.

"Opiate" means any dangerous substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under section 3 of this act, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L. , except the seeds thereof.

"Person" means any corporation, association, partnership, trust, other institution or entity or one or more individuals. "Pharmacist" means a registered pharmacist of this State.

"Pharmacy owner" means the owner of a store or other place of business where controlled dangerous substances are compounded or dispensed by a registered pharmacist; but nothing in this chapter contained shall be construed as conferring on a person who is not registered or licensed as a pharmacist any authority, right or privilege that is not granted to him by the pharmacy laws of this State.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, veterinarian, scientific investigator, laboratory, pharmacy, hospital or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance in the course of professional practice or research in this State.

(a) "Physician" means a physician authorized by law to practice medicine in this or any other state and any other person authorized by law to treat sick and injured human beings in this or any other state and

(b) "Veterinarian" means a veterinarian authorized by law to practice veterinary medicine in this State.

(c) "Dentist" means a dentist authorized by law to practice dentistry in this State.

(d) "Hospital" means any federal institution, or any institution for the care and treatment of the sick and injured, operated or approved by the appropriate State department as proper to be entrusted with the custody and professional use of controlled dangerous substances.

(e) "Laboratory" means a laboratory to be entrusted with the custody of narcotic drugs and the use of controlled dangerous substances for scientific, experimental and medical purposes and for

purposes of instruction approved by the [State] Department of Health and Senior Services.

"Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled dangerous substance.

"Immediate precursor" means a substance which the [State] Department of Health] division has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled dangerous substance, the control of which is necessary to prevent, curtail, or limit such manufacture.

"State" means the State of New Jersey.

"Ultimate user" means a person who lawfully possesses a controlled dangerous substance for his own use or for the use of a member of his household or for administration to an animal owned by him or by a member of his household.

(cf: P.L.1985, c.134, s.1)

2. Section 3 of P.L.1970, c.226 (C.24:21-3) is amended to read as follows:

3. Authority to control. a. The [commissioner] director shall administer the provisions of [this act and] P.L.1970, c.226 (C.24:21-1 et seq.), as amended and supplemented, as provided herein. The director may add substances to or delete or reschedule all substances enumerated in the schedules in sections 5 through [8] 8.1 of [this act] P.L.1970, c.226, as amended and supplemented (C.24:21-5 through 24:21-8.1). In determining whether to control a substance, the [commissioner] director shall consider the following:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effect, if known;

(3) State of current scientific knowledge regarding the substance;

(4) Its history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) What, if any, risk there is to the public health;

(7) Its psychic or physiological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under this article.

After considering the above factors, the [commissioner] director shall make findings with respect thereto and shall issue an order controlling the substance if he finds that the substance has a potential for abuse.

b. If the [commissioner] director designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

c. If any substance is designated, rescheduled or deleted as a controlled dangerous substance under Federal law and notice thereof is given to the ⟦commissioner⟧ director, the ⟦commissioner⟧ director shall similarly control the substance under ⟦this act⟧ P.L.1970, c.226, as amended and supplemented, after the expiration of 30 days from publication in the Federal Register of a final order designating a substance as a controlled dangerous substance or rescheduling or deleting a substance, unless within that 30-day period, the ⟦commissioner⟧ director objects to inclusion, rescheduling, or deletion. In that case, the ⟦commissioner⟧ director shall cause to be published in the New Jersey Register and made public the reasons for his objection and shall afford all interested parties an opportunity to be heard. At the conclusion of any such hearing, the ⟦commissioner⟧ director shall publish and make public his decision, which shall be final unless the substance is specifically otherwise dealt with by an act of the Legislature. Upon publication of objection to inclusion or rescheduling under ⟦this act⟧ P.L.1970, c.226 (C.24:21-1 et seq.) by the ⟦commissioner⟧ director, control of such substance under this section shall automatically be stayed until such time as the ⟦commissioner⟧ director makes public his final decision.

The ⟦Commissioner of Health⟧ director may by regulation exclude any nonnarcotic substance from a schedule if such substance may, under the provisions of Federal or State law, be lawfully sold over the counter without a prescription, unless otherwise controlled pursuant to rules and regulations promulgated by the ⟦department⟧ division.

d. The ⟦State Department of Health⟧ director shall update and republish the schedules in sections 5 through ⟦8⟧ 8.1 of P.L.1970, c.226, as amended and supplemented (C.24:21-5 through 24:21-8.1) ⟦on a semiannual basis for 2 years from the effective date of this act and thereafter on an annual basis⟧ periodically.

(cf: P.L.1970, c.226, s.3)

3. Section 5 of P.L.1970, c. 226 (C.24:21-5) is amended to read as follows:

5. Schedule I.

a. Tests. The ⟦commissioner⟧ director shall place a substance in Schedule I if he finds that the substance: (1) has high potential for abuse; and (2) has no accepted medical use in treatment in the United States; or lacks accepted safety for use in treatment under medical supervision.

b. The controlled dangerous substances listed in this section are included in Schedule I, subject to any revision and republishing by the ⟦commissioner⟧ director pursuant to subsection d. of section

【3d】 3 of P.L.1970, c.226 (C.24:21-3), and except to the extent provided in any other schedule.

c. Any of the following opiates, including their isomers, esters, and ethers, unless specifically excepted, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

(1) Acetylmethadol
(2) Allylprodine
(3) Alphacetylmethadol
(4) Alphameprodine
(5) Alphamethadol
(6) Benzethidine
(7) Betacetylmethadol
(8) Betameprodine
(9) Betamethadol
(10) Betaprodine
(11) Clonitazene
(12) Dextromoramide
(13) Dextrorphan
(14) Diampromide
(15) Diethylthiambutene
(16) Dimenoxadol
(17) Dimepheptanol
(18) Dimethylthiambutene
(19) Dioxaphetyl butyrate
(20) Dipipanone
(21) Ethylmethylthiambutene
(22) Etonitazene
(23) Etoxeridine
(24) Furethidine
(25) Hydroxypethidine
(26) Ketobemidone
(27) Levomoramide
(28) Levophenacylmorphan
(29) Morpheridine
(30) Noracymethadol
(31) Norlevorphanol
(32) Normethadone
(33) Norpipanone
(34) Phenadoxone
(35) Phenampromide
(36) Phenomorphan
(37) Phenoperidine
(38) Piritramide
(39) Proheptazine
(40) Properidine
(41) Racemoramide

(42) Trimeperidine.

d. Any of the following narcotic substances, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine
(2) Acetylcodone
(3) Acetyldihydrocodeine
(4) Benzylmorphine
(5) Codeine methylbromide
(6) Codeine-N-Oxide
(7) Cyprenorphine
(8) Desomorphine
(9) Dihydromorphine
(10) Etorphine
(11) Heroin
(12) Hydromorphinol
(13) Methyldesorphine
(14) Methylhydromorphine
(15) Morphine methylbromide
(16) Morphine methylsulfonate
(17) Morphine-N-Oxide
(18) Myrophine
(19) Nicocodeine
(20) Nicomorphine
(21) Normorphine
(22) Phoclodine
(23) Thebacon.

e. Any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine
(2) 5-methoxy-3,4-methylenedioxy amphetamine
(3) 3,4,5-trimethoxy amphetamine
(4) Bufotenine
(5) Diethyltryptamine
(6) Dimethyltryptamine
(7) 4-methyl-2,5-dimethoxylamphetamine
(8) Ibogaine
(9) Lysergic acid diethylamide
(10) Marihuana
(11) Mescaline
(12) Peyote
(13) N-ethyl-3-piperidyl benzilate
(14) N-methyl-3-piperidyl benzilate

(15) Psilocybin
(16) Psilocyn
(17) Tetrahydrocannabinols.
(cf: P.L.1970, c.226, s.5)

4. Section 6 of P.L.1970, c.226 (C.24:21-6) is amended to read as follows:

6. Schedule II.

a. Tests. The [commissioner] director shall place a substance in Schedule II if he finds that the substance: (1) has high potential for abuse; (2) has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and (3) abuse may lead to severe psychic or physical dependence.

b. The controlled dangerous substances listed in this section are included in Schedule II, subject to any revision and republishing by the [commissioner] director pursuant subsection d. of section [3d] 3 of P.L.1970, c.226 (C.24:21-3), and except to the extent provided in any other schedule.

c. Any of the following substances except those narcotic drugs listed in other schedules whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause 1, except that these substances shall not include the isoquinaline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extractions which do not contain cocaine or ecogine.

d. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, unless specifically excepted, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine
(2) Anileridine
(3) Bezitramide
(4) Dihydrocodeine
(5) Diphenoxylate

(6) Fentanyl
(7) Isomethadone
(8) Levomethorphan
(9) Levorphanol
(10) Metazocine
(11) Methadone
(12) Methadone--Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane
(13) Moramide--Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid
(14) Pethidine
(15) Pethidine--Intermediate--A, 4-cyano-1-methyl-4-phenylpiperidine
(16) Pethidine--Intermediate--B, ethyl-4-phenylpiperidine-4-carboxylate
(17) Pethidine--Intermediate--C, 1-methyl-4-phenylpiperidine-4-carboxylic acid
(18) Phenazocine
(19) Piminodine
(20) Racemethorphan
(21) Racemorphan.
(cf: P.L.1970, c.226, s.6)

5. Section 7 of P.L. 1970, c. 226 (C24:21-7) is amended to read as follows:

7. Schedule III.

a. Tests. The [commissioner] director shall place a substance in Schedule III if he finds that the substance: (1) has a potential for abuse less than the substances listed in Schedules I and II; (2) has currently accepted medical use in treatment in the United States; and (3) abuse may lead to moderate or low physical dependence or high psychological dependence.

b. The controlled dangerous substances listed in this section are included in Schedule III, subject to any revision and republishing by the [commissioner] director pursuant to subsection d. of section [3d.] 3 of P.L.1970, c.226 (C.24:21-3), and except to the extent provided in any other schedule.

c. Any material, compound, mixture, or preparation which contains any quantity of the following substances associated with a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
(2) Phenmetrazine and its salts.
(3) Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.
(4) Methylphenidate.

d. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances which are specifically listed in other schedules

(2) Chlorhexadol

(3) Glutethimide

(4) Lysergic acid

(5) Lysergic acid amide

(6) Methyprylon

(7) Phencyclidine

(8) Sulfondiethylmethane

(9) Sulfonethylmethane

(10) Sulfonmethane

(11) Ketamine hydrochloride.

e. Nalorphine.

f. Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.80 grams of codeine or any of its salts per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.80 grams of codeine or any of its salts per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone or any of its salts per 100 milliliters or not more than 15 milligrams per dosage unit, with a four-fold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone or any of its salts per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.80 grams of dihydrocodeine or any of its salts per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine or any of its salts per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium or any of its salts per 100 milliliters or per 100 grams, or not more than 25 milligrams per

dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine or any of its salts per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

g. The [commissioner] director may by regulation except any compound, mixture, or preparation containing any stimulant or depressant substance listed in subsections a. and b. of this schedule from the application of all or any part of this act if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system; provided, that such admixtures shall be included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a stimulant or depressant effect on the central nervous system.

(cf: P.L.1997, c.193, s.1)

6. Section 8 of P.L.1970, c.226, (C.24:21-8) is amended to read as follows:

8. Schedule IV.

a. Tests. The [commissioner] director shall place a substance in Schedule IV if he finds that the substance: (1) has low potential for abuse relative to the substances listed in Schedule III; (2) has currently accepted medical use in treatment in the United States; and (3) may lead to limited physical dependence or psychological dependence relative to the substances listed in Schedule III.

b. The controlled dangerous substances listed in this section are included in Schedule IV.

c. Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

(1) Barbital

(2) Chloral betaine

(3) Chloral hydrate

(4) Ethchlorovynol

(5) Ethinamate

(6) Methohexital

(7) Meprobamate

(8) Methylphenobarbital

(9) Paraldehyde

(10) Petrichloral

(11) Phenobarbital

d. The [commissioner] director may except by rule any compound, mixture, or preparation containing any depressant substance listed in subsection c. from the application of all or any

part of this act if the compound, mixture or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.
(cf: P.L.1971, c.3, s.3)

7. Section 4 of P.L.1971, c.3 (C.24:21-8.1) is amended to read as follows:

4. Schedule V.

a. Tests. The [commissioner] director shall place a substance in Schedule V if he finds that the substance: (1) has low potential for abuse relative to the substances listed in Schedule IV; (2) has currently accepted medical use in treatment in the United States; and (3) has limited physical dependence or psychological dependence liability relative to the substances listed in Schedule IV.

b. The controlled dangerous substances listed in this section are included in Schedule V.

c. Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine or any of its salts per 100 milliliters or per 100 grams;

(2) Not more than 100 milligrams of dihydrocodeine or any of its salts per 100 milliliters or per 100 grams;

(3) Not more than 50 milligrams of ethylmorphine or any of its salts per 100 milliliters or per 100 grams;

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) Not more than 100 milligrams of opium or any of its salts per 100 milliliters or per 100 grams.
(cf: P.L.1971, c.3, s.4)

8. Section 9 of P.L.1970, c.226 (C.24:21-9) is amended to read as follows:

9. Rules and regulations. The [commissioner] director is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled dangerous substances within this State.
(cf: P.L.1970, c.226, s.9)

9. Section 10 of P.L.1970, c.226 (C.24:21-10) is amended to read as follows:

10. Registration requirements. a. Every person who manufactures, distributes, or dispenses any controlled dangerous substance within this State or who proposes to engage in the manufacture, distribution, or dispensing of any controlled dangerous substance within this State, shall obtain [annually] a registration issued by the [State Department of Health] division in accordance with rules and regulations promulgated by it.

b. Persons registered by the [commissioner] director under this act to manufacture, distribute, dispense, or conduct research with controlled dangerous substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this article.

c. The following persons shall not be required to register and may lawfully have under their control or possess controlled dangerous substances under the provisions of [this act] P.L.1970, c.226 (C.24:21-1 et seq.), as amended and supplemented; provided, however, that nothing in this section shall be construed as conferring on a person who is not registered or licensed as a practitioner or as a pharmacist any authority, right or privilege that is not granted him by the laws of this State:

(1) An agent, or an employee thereof, of any registered manufacturer, distributor, or dispenser of any controlled dangerous substance if such agent is acting in the usual course of his business or employment;

(2) A common carrier or warehouseman, or an employee thereof, whose possession of any controlled dangerous substance is in the usual course of his business or employment;

(3) An ultimate user or a person in possession of any controlled dangerous substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance;

(4) Peace officers or employees in the performance of their official duties requiring possession or control of controlled dangerous substances; or to temporary incidental possession by employees or agents of persons lawfully entitled to possession, or by persons whose possession is authorized for the purpose of aiding peace officers in performing their official duties.

d. The [commissioner] director may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

e. A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled dangerous substances.

f. The [commissioner] director is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.
(cf: P.L.1971, c.3, s.5)

10. Section 11 of P.L.1970, c.226 (C.24:21-11) is amended to read as follows:

11. Registration. a. The [State Department of Health] division shall not register an applicant to manufacture or distribute controlled dangerous substances included in Schedules I through IV of article 2 of [this act] P.L.1970, c.226 (C.24:21-3 et seq.), as amended and supplemented, unless it determines that the issuance of such registration is consistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled dangerous substances into other than legitimate medical, scientific, or industrial channels;

(2) Compliance with applicable State and local laws;

(3) Any convictions of the applicant under any Federal and State laws relating to any controlled dangerous substance;

(4) Past experience in the manufacture of controlled dangerous substances, and the existence in the applicant's establishment of effective controls against diversion;

(5) Furnishing by the applicant false or fraudulent material in any application filed under this act;

(6) Suspension or revocation of the applicant's Federal registration to manufacture, distribute, or dispense controlled dangerous substances as authorized by Federal law; and

(7) Such other factors as may be relevant to and consistent with the public health and safety.

b. Registration granted under subsection a. of this section shall not entitle a registrant to manufacture and distribute controlled dangerous substances in Schedule I or II other than those specified in the registration.

c. Practitioners shall be registered to dispense substances in Schedules II through IV if they are authorized to dispense or conduct research under the law of this State. The [commissioner] director need not require separate registration under this article for practitioners engaging in research with nonnarcotic controlled dangerous substances in Schedules II through IV where the registrant is already registered under this article in another capacity. Practitioners registered under Federal law to conduct research in Schedule I substances are permitted to conduct research in Schedule I substances within this State upon furnishing the [commissioner] director evidence of that Federal registration.

d. Compliance by manufacturers and distributors with the provisions of the Federal law respecting registration (excluding fees) entitles them to be registered under [this act] P.L.1970, c.226 (C.24:21-1 et seq.), as amended and supplemented.

e. The [State Department of Health] division shall initially permit persons to register who own or operate any establishment engaged in the manufacture, distribution or dispensing of any controlled dangerous substances prior to the effective date of [this act] P.L.1970, c.226, as amended and supplemented, and who are registered or licensed by the State.

f. An incorporated humane society or a licensed animal control facility may designate an officer, a member of its board of trustees, the owner, the operator or the manager as its duly authorized agent. The [State Department of Health] division shall, consistent with the public interest, register such duly authorized agent for the limited purpose of buying, possessing, and dispensing to registered and certified personnel sodium pentobarbital to euthanize injured, sick, homeless and unwanted domestic pets or domestic or wild animals. The duly authorized agent shall file, on a quarterly basis, a report of any purchase, possession and use of sodium pentobarbital, which report shall be certified by the humane society or animal control facility as to its accuracy and validity. This report shall be in addition to any other recordkeeping and reporting requirements of State and Federal law and regulation.

The [State Department of Health] division shall adopt rules and regulations providing for the registration and certification of any individual who, under the direction of the duly authorized and registered agent of an incorporated humane society or licensed animal control facility, uses sodium pentobarbital to euthanize injured, sick, homeless and unwanted domestic pets or domestic or wild animals. The [State Department of Health] division may also adopt such other rules and regulations as shall provide for the safe and efficient use of sodium pentobarbital by animal control facilities and humane societies. Nothing herein shall be deemed to waive any other requirement imposed on animal control facilities and humane societies by State and Federal law and regulation.

(cf: P.L.1979, c.204, s.1)

11. Section 12 of P.L.1970, c.226 (C.24:21-12) is amended to read as follows:

12. Denial, revocation, or suspension of revocation. a. A registration pursuant to section 11 of P.L.1970, c.226 (C.24:21-11) to manufacture, distribute, or dispense a controlled dangerous substance, may be suspended or revoked by the [commissioner] director upon a finding that the registrant:

(1) Has materially falsified any application filed pursuant to [this act] P.L.1970, c.226 (C.24:21-1 et seq.), as amended and

supplemented, or required by [this act] P.L.1970, c.226, as amended and supplemented; or

(2) Has been convicted of an indictable offense under [this act] P.L.1970, c.226, as amended and supplemented, or any law of the United States, or of any State, relating to any substance defined herein as a controlled dangerous substance; or

(3) Has violated or failed to comply with any duly promulgated regulation of the [commissioner] director and such violation or failure to comply reflects adversely on the licensee's reliability and integrity with respect to controlled dangerous substances; or

(4) Has had his Federal registration suspended or revoked by competent Federal authority and is no longer authorized by Federal law to engage in the manufacturing, distribution, or dispensing of controlled dangerous substances; or

(5) Has had his registration suspended or revoked by competent authority of another state for violation of its laws or regulations comparable to those of this State relating to the manufacture, distribution or dispensing of controlled dangerous substances.

b. The [commissioner] director may limit revocation or suspension of a registration to the particular controlled dangerous substance with respect to which grounds for revocation or suspension exist.

c. Before taking action pursuant to this section or pursuant to a denial of registration under section 11 of P.L.1970, c.226 (C.24:21-11), the [commissioner] director shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the [commissioner] director at a time and place stated in the order, but in no event less than 30 days after the date of receipt of the order unless an earlier date is requested by the applicant or registrant and agreed to by the [commissioner] director. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with the provisions of the "Administrative Procedure Act," P.L.1968, c.410 (C. 52:14B-1 et seq.). Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under [this act] P.L.1970, c.226, as amended and supplemented, or any law of the State.

d. The [commissioner] director may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section in cases where he finds that there is an imminent danger to the public health or safety. Such suspensions shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the

[commissioner] director or dissolved by a court of competent jurisdiction.

e. In the event the [commissioner] director suspends or revokes a registration granted under section 11 of P.L.1970, c.226 (C.24:21-11), all controlled dangerous substances owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may in the discretion of the [commissioner] director be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled dangerous substances may be forfeited to the State.

f. The [commissioner] director shall promptly notify the [Bureau of Narcotics and Dangerous Drugs] Drug Enforcement Administration of all orders suspending or revoking registration and all forfeitures of controlled dangerous substances.

(cf: P.L.1970, c.226, s.12)

12. Section 13 of P.L.1970, c.226 (C.24:21-13) is amended to read as follows:

13. Records of registrants. Persons registered to manufacture, distribute, or dispense controlled dangerous substances under [this act] P.L.1970, c.226 (C.24:21-1 et seq.), as amended and supplemented, shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of Federal law and with such additional rules as may be issued by the [commissioner] director.

(cf: P.L.1970, c.226, s.13)

13. Section 14 of P.L.1970, c.226 (C.24:21-14) is amended to read as follows:

14. Order forms. a. Controlled dangerous substances in Schedule I and II shall be distributed only by a registrant, pursuant to an official written order form, clearly identifying it as covering or relating to Schedule I and Schedule II, or either thereof, controlled dangerous substances and bearing the registration number of the registrant. [Except as provided herein, compliance] Compliance with Federal law respecting order forms shall be deemed compliance with this section.

b. A pharmacist, only upon an official written order, may sell to a practitioner in quantities not exceeding one ounce at any one time, aqueous or oleaginous solutions compounded by him of which the content of narcotic drugs or other controlled dangerous substances does not exceed a proportion greater than 20% of the complete solution, to be used for medical purposes.

c. An official written order for any controlled dangerous substance in Schedule I or Schedule II shall be signed in triplicate by the person giving said order or by his duly authorized agent. The original and triplicate shall be presented to the person who sells or dispenses the controlled dangerous substance or substances named therein. In the event of the acceptance of such order by said person, except as may be otherwise required by rule, regulation, or order of the **[**commissioner**]** director, each party to the transaction shall preserve his copy of such order for a period of **[**2**]** two years, in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter.

d. Use of an official written order in electronic form shall comply with the requirements of State law and regulations.

(cf: P.L.1970, c.226, s.14)

14. Section 15 of P.L.1970, c.226 (C.24:21-15) is amended to read as follows:

15. Prescriptions. a. Except when dispensed directly in good faith by a practitioner, other than a pharmacist, in the course of his professional practice only, to an ultimate user, no controlled dangerous substance included in Schedule II, which is a prescription drug as defined in **[**R.S.45:14-14**]** section 2 of P.L.2003, c.280 (C.45:14-41), may be dispensed without the written prescription of a practitioner; provided that in emergency situations, as prescribed by the **[**State Department of Health**]** division by regulation, such drug may be dispensed upon oral prescription reduced promptly to writing and filed by the pharmacist, if such oral prescription is authorized by Federal law. Prescriptions shall be retained in conformity with the requirements of section 13 of **[**this act**]** P.L.1970, c.226 (C.24:21-13). No prescription for a Schedule II substance may be refilled.

b. Except when dispensed directly in good faith by a practitioner, other than a pharmacist, in the course of his professional practice only, to an ultimate user, no controlled dangerous substance included in Schedule III and IV which is a prescription drug as defined in **[**R.S.45:14-14**]** section 2 of P.L.2003, c.280 (C.45:14-41) may be dispensed without a written or oral prescription. Such prescription may not be filled or refilled more than **[**6**]** six months after the date thereof or be refilled more than **[**5**]** five times after the date of the prescription, unless renewed by the practitioner.

c. No controlled dangerous substance included in Schedule V may be distributed or dispensed other than for a valid and accepted medical purpose.

d. A practitioner other than a veterinarian who prescribes a controlled dangerous substance in good faith and in the course of

his professional practice may administer the same or cause the same to be administered by a nurse or intern under his direction and supervision.

e. A veterinarian who prescribes a controlled dangerous substance not for use by a human being in good faith and in the course of his professional practice may administer the same or cause the same to be administered by an assistant or orderly under his direction and supervision.

f. A person who has obtained a controlled dangerous substance from the prescribing practitioner for administration to a patient during the absence of the practitioner shall return to the practitioner any unused portion of the substance when it is no longer required by the patient or when its return is requested by the practitioner.

g. Whenever it appears to the **[**State Department of Health**]** director that a drug not considered to be a prescription drug under existing State law should be so considered because of its abuse potential, it shall so advise the New Jersey State Board of Pharmacy and furnish to it all available data relevant thereto.

(cf: P.L.1971, c.3, s.7)

15. Section 17 of P.L.1970, c.226 (C.24:21-17) is amended to read as follows:

17. Form of label to be used by pharmacists; altering or removing label. Whenever a pharmacist sells or dispenses any controlled dangerous substance on a prescription issued by a practitioner, he shall affix to the container in which such drug is sold or dispensed, a label showing his own name, address, and registry number, or the name, address, and registry number of the pharmacist or pharmacy owner for whom he is lawfully acting; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the practitioner by whom the prescription was issued; the brand name or generic name of the drug dispensed unless the prescriber states otherwise on the prescription, such directions as may be stated on the prescription and such directions as may be required by rules or regulations promulgated by the **[**commissioner**]** director.

No person shall alter, deface, or remove any label so affixed as long as any of the original contents remain.

(cf: P.L.1986, c.75, s.1)

16. Section 31 of P.L.1970, c.226 (C.24:21-31) is amended to read as follows:

31. Powers of enforcement personnel. a. It is hereby made the duty of the **[**State Department of Health**]** division, its officers, agents, inspectors and representatives, and of all peace officers within the State, and of the Attorney General and all county prosecutors, to enforce all provisions of **[**this act**]** P.L.1970, c.226

(C.24:21-1 et seq.), as amended and supplemented, except those specifically delegated, and to cooperate with all agencies charged with the enforcement of the laws of the United States, of this State, and of all other states, relating to narcotic drugs or controlled dangerous substances, and it shall be the duty of the New Jersey Board of Pharmacy in the Division of [Professional Boards] Consumer Affairs in the Department of Law and Public Safety, its officers, agents, inspectors and representatives also to assist the [State Department of Health] division, peace officers and county prosecutors in the enforcement of all provisions of [this act] P.L.1970, c.226, as amended and supplemented, relating to the handling of controlled dangerous substances by pharmacy owners and pharmacists.

b. Authority is hereby granted to the [Commissioner of Health] director:

(1) To promulgate all necessary rules and regulations for the efficient enforcement of [this act] P.L.1970, c.226, as amended and supplemented;

(2) To promulgate, insofar as applicable, regulations from time to time promulgated by the Attorney General of the United States;

(3) To promulgate an order relative to any controlled dangerous substance under [this act] P.L.1970, c.226, as amended and supplemented, when the delay occasioned by acting through promulgation of a regulation would constitute an imminent danger to the public health or safety.

(a) An order of the [commissioner] director shall take effect immediately, but it shall expire [120] 270 days after promulgation thereof. Rules and regulations pursuant to such order may be adopted and promulgated by the [commissioner] director but they shall not take effect until he has given due notice of his intention to take such action and has held a public hearing.

(b) Any person who denies that a drug or pharmaceutical preparation is properly subject to an order by the [commissioner] director which applies the provisions of [this act] P.L.1970, c.226, as amended and supplemented, to such drug or pharmaceutical preparation, may apply to the [commissioner] director for a hearing which must be afforded, except where a drug or pharmaceutical preparation has been the subject of a prior hearing or determination by the [commissioner] director, in which case a hearing shall be discretionary with the [commissioner] director. In such case a decision must be rendered by the [commissioner] director or his designee within 48 hours of the request for a hearing. If the petitioning party is aggrieved by the decision, he shall have the right to apply for injunctive relief against the order. Jurisdiction for such injunctive relief shall be in the Superior Court of New Jersey by way of summary proceedings.

c. In addition to the powers set forth in subsection a., of this section, any officer or employee of the [State Department of Health] division designated by the [commissioner] director may:

(1) Execute search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses issued under the authority of this State;

(2) Make seizures of property pursuant to the provisions of this act; and

(3) Perform such other law enforcement duties as may bedesignated by the [commissioner] director with the approval of the Attorney General.

(cf: P.L.1970, c.226, s.31)

17. Section 32 of P.L.1970, c.226 (C.24:21-32) is amended to read as follows:

32. Administrative inspections and warrants. a. Issuance and execution of administrative inspection warrants shall be as follows:

(1) Any judge of a court having jurisdiction in the municipality where the inspection or seizure is to be conducted, may, upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by [this act] P.L.1970, c.226 (C.24:21-1 et seq.), as amended and supplemented, or regulations thereunder, and seizures of property appropriate to such inspections. For the purposes of this section, "probable cause" means a valid public interest in the effective enforcement of [the act] P.L.1970, c.226, as amended and supplemented, or regulations sufficient to justify administrative inspection of the area, premises, building or conveyance in the circumstances specified in the application for the warrant;

(2) A warrant shall issue only upon an affidavit of an officer or employee duly designated and having knowledge of the facts alleged, sworn to before the judge and establishing the grounds for issuing the warrant. If the judge is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall identify the item or types of property to be seized, if any. The warrant shall be directed to a person authorized by [section 3] section 31 of P.L.1970, c.226 (C.24:21-31) to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified, and where appropriate, shall direct the seizure of the property specified. The

warrant shall direct that it be served during normal business hours. It shall designate the judge to whom it shall be returned;

(3) A warrant issued pursuant to this section must be executed and returned within 10 days of its date. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken or shall leave the copy and receipt at the place from which the property was taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if they are present, or in the presence of at least one credible person other than the person executing the warrant. The clerk of the court, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and to the applicant for the warrant; and

(4) The judge who has issued a warrant under this section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall cause them to be filed with the court which issued such warrant.

b. The **[**commissioner**]** director is authorized to make administrative inspections of controlled premises in accordance with the following provisions:

(1) For the purposes of this article only, "controlled premises" means:

(a) Places where persons registered or exempted from registration requirements under **[**this act**]** P.L.1970, c.226, as amended and supplemented, are required to keep records, and

(b) Places including factories, warehouses, establishments, and conveyances where persons registered or exempted from registration requirements under **[**this act**]** P.L.1970, c.226, as amended and supplemented, are permitted to hold, manufacture, compound, process, sell, deliver, or otherwise dispose of any controlled dangerous substance.

(2) When so authorized by an administrative inspection warrant issued pursuant to paragraph (1) of subsection a. **[**(1)**]** of this section, an officer or employee designated by the **[**commissioner**]** director upon presenting the warrant and appropriate credentials to the owner, operator, or agent in charge, shall have the right to enter controlled premises for the purpose of conducting an administrative inspection.

(3) When so authorized by an administrative inspection warrant, an officer or employee designated by the **[**commissioner**]** director shall have the right:

(a) To inspect and copy records required by [this act] P.L.1970, c.226, as amended and supplemented, to be kept;

(b) To inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished material, containers and labeling found therein, and, except as provided in paragraph (5) of subsection b.[(5)] of this section, all other things therein including records, files, papers, processes, controls, and facilities bearing on violation of [this act] P.L.1970, c.226, as amended and supplemented; and

(c) To inventory any stock of any controlled dangerous substance therein and obtain samples of any such substance.

(4) This section shall not be construed to prevent entries and administrative inspections (including seizures of property) without a warrant:

(a) With the consent of the owner, operator or agent in charge of the controlled premises;

(b) In situations presenting imminent danger to health or safety;

(c) In situations involving inspection of conveyances where there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(d) In any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; and,

(e) In all other situations where a warrant is not constitutionally required.

(5) Except when the owner, operator, or agent in charge of the controlled premises so consents in writing, no inspection authorized by this section shall extend to:

(a) Financial data;

(b) Sales data other than shipment data;

(c) Pricing data;

(d) Personnel data; or

(e) Research data.

(cf: P.L.1970, c.226, s.32)

18. Section 34 of P.L.1970, c.226 (C.24:21-34) is amended to read as follows:

34. Cooperative arrangements. a. The [commissioner] director may cooperate with Federal and other State agencies in discharging his responsibilities concerning traffic in dangerous substances and in suppressing the abuse of dangerous substances. To this end, he is authorized to:

(1) Except as otherwise provided by law, arrange for the exchange of information between government officials concerning the use and abuse of dangerous substances; provided, however, that in no case shall any officer having knowledge by virtue of his office of any such prescription, order or record divulge such knowledge, except in connection with a prosecution or proceeding in court or

before a licensing board or officer to which prosecution or proceeding the person to whom the records relate, is a party;

(2) Coordinate and cooperate in training programs on dangerous substances law enforcement at the local and State levels;

(3) Conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled dangerous substances may be extracted.

b. Results, information, and evidence received from the **[**Bureau of Narcotics and Dangerous Drugs**]** Drug Enforcement Administration relating to the regulatory functions of **[**this act**]** P.L.1970, c.226 (C.24:21-1 et seq.), as amended and supplemented, including results of inspections conducted by that agency, may be relied upon and acted upon by the **[**commissioner**]** director in conformance with his regulatory functions under **[**this act**]** P.L.1970, c.226, as amended and supplemented.

(cf: P.L.1970, c.226, s.34)

19. Section 36 of P.L.1970, c.226 (C.24:21-36) is amended to read as follows:

36. Reports of convictions of manufacturers and practitioners. Whenever a manufacturer or practitioner is convicted of violating any provision of **[**this act**]** P.L.1970, c.226 (C.24:21-1 et seq.), as amended and supplemented, or of a rule or regulation issued thereunder or of any offense defined in chapters 35 or 36 of Title 2C of the New Jersey Statutes, the court shall cause a copy of the judgment and sentence and opinion of the court, if any, to be sent to the **[**State Department**]** division or professional board, as the case may be, by which the defendant was registered or licensed.

(cf: P.L.1987, c.106, s.22)

20. Section 38 of P.L.1970, c.226 (C.24:21-38) is amended to read as follows:

38. Judicial review. All final determinations, findings and conclusions of the **[**commissioner**]** director under **[**this act**]** P.L.1970, c.226 (C.24:21-1 et seq.), as amended and supplemented, shall be final and conclusive decisions of the matters involved, subject to the provisions for judicial review provided by the Rules of Court.

(cf: P.L.1970, c.226, s.38)

21. Section 39 of P.L.1970, c.226 (C.24:21-39) is amended to read as follows:

39. Reports by practitioners of drug dependent persons. Every practitioner, within 24 hours after determining that a person is a drug dependent person by reason of the use of a controlled dangerous substance for purposes other than the treatment of sickness or injury prescribed and administered as authorized by law,

shall report such determination verbally or by mail to the [Commissioner of the State Department of Health] director. Such a report by a physician shall be confidential and shall not be admissible in any criminal proceeding. The [commissioner] director, in his discretion, may also treat any other reports submitted under this section as confidential if he determines that it is in the best interest of the drug dependent person and the public health and welfare. A practitioner who fails to make a report required by this section is a disorderly person.
(cf: P.L.1970, c.226, s.39)

22. Section 20 of P.L.2003, c.280 (C.45:14-59) is amended to read as follows:

20. The Division of Consumer Affairs in the Department of Law and Public Safety shall establish the format for uniform, non-reproducible, non-erasable safety paper prescription blanks, to be known as New Jersey Prescription Blanks, which format shall include an identifiable logo or symbol that will appear on all prescription blanks. The prescription blanks for each prescriber or health care facility shall be numbered consecutively and if the prescriber or health care facility has a National Provider Identifier, the prescription blank shall include the National Provider Identifier. The division shall approve a sufficient number of vendors to ensure production of an adequate supply of New Jersey Prescription Blanks for practitioners and health care facilities statewide.
(cf: P.L.2003, c.280, s.20)

23. (New section) a. There is established in the Department of the Treasury a special, dedicated nonlapsing fund to be known as the "Controlled Dangerous Substances Administration and Enforcement Fund." The fund shall be the depository for fees, cost recoveries and penalties collected in connection with the "New Jersey Controlled Dangerous Substances Act," P.L.1970, c.226 (C.24:21-1 et seq.), as amended and supplemented, and the Prescription Monitoring Program established pursuant to P.L. , c. (C.)(Pending before the Legislature as this bill). Monies deposited in the fund and the interest earned thereon shall be used for the collection of information, administration and enforcement of laws relating to controlled dangerous substances.

b. The Legislature shall annually appropriate monies from the fund to the Division of Consumer Affairs in the Department of Law and Public Safety for the collection of information, administration, and enforcement of laws relating to controlled dangerous substances.

24. (New section) [1]Definitions.[1] As used in sections 25 through [2][29] 30[2] of P.L. , c. (C.)(pending before the Legislature as this bill):

[1][Definitions.][1]

"Controlled dangerous substance" means any substance that is listed in Schedules II, III and IV of the schedules provided under the "New Jersey Controlled Dangerous Substances Act," P.L.1970, c.226 (C.24:21-1 et seq.). Controlled dangerous substance also means any substance that is listed in Schedule V under the "New Jersey Controlled Dangerous Substances Act" when the director has determined that reporting Schedule V substances is required by federal law, regulation or funding eligibility.

"Director" means the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

"Division" means the Division of Consumer Affairs in the Department of Law and Public Safety.

"Practitioner" means an individual currently licensed, registered or otherwise authorized by this State or another state to prescribe drugs in the course of professional practice.

"Ultimate user" means a person who has obtained from a dispenser and possesses for his own use, or for the use of a member of his household or an animal owned by him or by a member of his household, a controlled dangerous substance.

25. (New section) Prescription Monitoring Program; requirements.

a. There is established the Prescription Monitoring Program in the Division of Consumer Affairs in the Department of Law and Public Safety. The program shall consist of an electronic system for monitoring controlled dangerous substances that are dispensed in or into the State by a pharmacist in an outpatient setting.

b. Each pharmacy permit holder shall submit, or cause to be submitted, to the division, by electronic means in a format and at such intervals as are specified by the director, information about each prescription for a controlled dangerous substance dispensed by the pharmacy that includes:

(1) The surname, first name, and date of birth of the patient for whom the medication is intended;

(2) The street address and telephone number of the patient;

(3) The date that the medication is dispensed;

(4) The number or designation identifying the prescription and the National Drug Code of the drug dispensed;

(5) The pharmacy permit number of the dispensing pharmacy;

(6) The prescribing practitioner's name and Drug Enforcement Administration registration number;

(7) The name, strength and quantity of the drug dispensed, the number of refills ordered, and whether the drug was dispensed as a refill or a new prescription;

(8) the date that the prescription was issued by the practitioner; [1]**[**and**]**[1]

(9) [1]the source of payment for the drug dispensed; and

(10)[1] such other information, not inconsistent with federal law, regulation or funding eligibility requirements, as the director determines necessary.

The pharmacy permit holder shall submit the information to the division with respect to the prescriptions dispensed during the reporting period not less frequently than every 30 days, or according to a schedule to be determined by the director if federal law, regulation or funding eligibility otherwise requires.

c. The division may grant a waiver of electronic submission to any pharmacy permit holder for good cause, including financial hardship, as determined by the director. The waiver shall state the format in which the pharmacy permit holder shall submit the required information.

d. The requirements of this act shall not apply to: the direct administration of a controlled dangerous substance to the body of an ultimate user; or the administration or dispensing of a controlled dangerous substance that is otherwise exempted as determined by the Secretary of Health and Human Services pursuant to the "National All Schedules Prescription Electronic Reporting Act of 2005," Pub.L.109-60.

26. (New section) Access to prescription information.

a. The division shall maintain procedures to ensure privacy and confidentiality of patients and that patient information collected, recorded, transmitted and maintained is not disclosed, except as permitted in this section[1], including, but not limited to, the use of a password-protected system for maintaining this information and permitting access thereto as authorized under sections 25 through [2]**[**29**]** 30[2] of P.L. , c. (C.)(pending before the Legislature as this bill), and a requirement that a person as listed in subsection d. of this section provide on-line affirmation of the person's intent to comply with the provisions of sections 25 through [2]**[**29**]**[2] 30 of P.L. , c. (C.)(pending before the Legislature as this bill) as a condition of accessing the information[1].

b. The prescription monitoring information submitted to the division shall be confidential and not be subject to public disclosure under P.L.1963, c.73 (C.47:1A-1 et seq.), or P.L.2001, c.404 (C.47:1A-5 et al.).

c. The division shall review the prescription monitoring information provided by a pharmacy permit holder pursuant to sections 25 through [2]**[**29**]** 30[2] of P.L. , c. (C.)(pending before

the Legislature as this bill). If the division determines that a violation of law or regulations, or a breach of the applicable standards of practice, may have occurred, the division shall notify the appropriate law enforcement agency or professional licensing board, and provide the prescription monitoring information required for an investigation.

d. The division may provide prescription monitoring information to the following persons:

(1) a practitioner authorized to prescribe, dispense or administer controlled dangerous substances who certifies that the request is for the purpose of providing health care to a current patient of the practitioner. Nothing in sections 25 through ²[29] 30² of P.L. , c. (C.)(pending before the Legislature as this bill) shall be construed to require or obligate a practitioner to access or check the prescription monitoring information prior to prescribing, dispensing or administering medications beyond that which may be required as part of the practitioner's professional practice;

(2) a pharmacist authorized to dispense controlled dangerous substances who certifies that the request is for the purpose of providing health care to a current patient. Nothing in sections 25 through ²[29] 30² of P.L. , c. (C.)(pending before the Legislature as this bill) shall be construed to require or obligate a pharmacist to access or check the prescription monitoring information prior to dispensing medications beyond that which may be required as part of the pharmacist's professional practice;

(3) a designated representative of the State Board of Medical Examiners, New Jersey State Board of Dentistry, New Jersey Board of Nursing, New Jersey State Board of Optometrists, New Jersey State Board of Pharmacy, State Board of Veterinary Medical Examiners, or any other board in this State or another state that regulates the practice of persons who are authorized to prescribe or dispense controlled dangerous substances, as applicable, who certifies that he is engaged in a bona fide specific investigation of a designated practitioner whose professional practice was or is regulated by that board;

(4) a State, federal or municipal law enforcement officer who is acting pursuant to a court order and certifies that the officer is engaged in a bona fide specific investigation of a designated practitioner or patient;

(5) a designated representative of a state Medicaid or other program who certifies that he is engaged in a bona fide investigation of a designated practitioner or patient;

(6) a properly convened grand jury pursuant to a subpoena properly issued for the records;

(7) authorized personnel of the division or vendor or contractor responsible for establishing and maintaining the program; and

(8) the controlled dangerous substance monitoring program in another state with which the division has established an interoperability agreement.

e. [1]A person listed in subsection d. of this section, as a condition of obtaining prescription monitoring information pursuant thereto, shall certify, by means of entering an on-line statement in a form and manner prescribed by regulation of the director, the reasons for seeking to obtain that information.

f. The division shall offer an on-line tutorial for those persons listed in subsection d. of this section, which shall, at a minimum, include: how to access prescription monitoring information; the rights and responsibilities of persons who are the subject of or access this information and the other provisions of sections 25 through [2]**[**29**]** 30[2] of P.L. , c. (C.)(pending before the Legislature as this bill) and the regulations adopted pursuant thereto, regarding the permitted uses of that information and penalties for violations thereof; and a summary of the requirements of the federal health privacy rule set forth at 45 CFR Parts 160 and 164 and a hypertext link to the federal Department of Health and Human Services website for further information about the specific provisions of the privacy rule.

g.[1] The director may provide nonidentifying prescription drug monitoring information to public or private entities for statistical, research or educational purposes.

[2]27. (New section) Prescription Monitoring Program; provisions for expansion.

a. Notwithstanding the provisions of section 25 of P.L. , c. (C.)(pending before the Legislature as this bill) to the contrary, the director may adopt a regulation to expand the program to include information about each prescription dispensed for a prescription drug that is not a controlled dangerous substance. In determining whether a prescription drug other than a controlled dangerous substance should be monitored, the director shall consider: the actual or relative potential for abuse; scientific evidence of its pharmacological effect, if known; the state of current scientific knowledge regarding the drug; its history and current pattern of abuse; the scope, duration and significance of abuse; what, if any, risk to the public health; and its psychic or physiological dependence liability. The regulation shall provide that the prescription drug shall be monitored for a period of time. At the conclusion of the monitoring period, the director shall publish and make public the decision of whether inclusion of the prescription drug in the program shall be permanent.

b. At the time the notice to expand the program pursuant to subsection a. is published in the New Jersey Register, the director shall provide a copy of the notice of proposed rule making to the

chairpersons of the standing legislative reference committees on health of the Senate and General Assembly.[2]

[2]**[**27.**]** 28.[2] (New section) Immunity from liability.

a. The division shall be immune from civil liability arising from inaccuracy of any of the information submitted to it pursuant to sections 25 through [2]**[**29**]** 30[2] of P.L. , c. (C.)(pending before the Legislature as this bill).

b. A pharmacy permit holder, pharmacist or practitioner shall be immune from civil liability arising from compliance with sections 25 through [2]**[**29**]** 30[2] of P.L. , c. (C.)(pending before the Legislature as this bill).

[2]**[**28.**]** 29.[2] (New section) Penalties.

a. A pharmacy permit holder, or a person designated by a pharmacy permit holder to be responsible for submitting data required by section 25 of P.L. , c. (C.) (pending before the Legislature as this bill), who knowingly fails to submit data as required, shall be subject to disciplinary action pursuant to section 8 of P.L.1978, c.73 (C.45:1-21) and may be subject to a civil penalty in an amount not to exceed $1,000 for repeated failure to comply with sections 25 through [2]**[**29**]** 30[2] of P.L. , c. (C.)(pending before the Legislature as this bill).

b. (1) A pharmacy permit holder, pharmacist or practitioner, or any other person or entity who knowingly discloses [1]or uses[1] prescription monitoring information in violation of the provisions of sections 25 through [2]**[**29**]** 30[2] of P.L. , c. (C.)(pending before the Legislature as this bill) shall be subject to a civil penalty in an amount not to exceed $10,000.

(2) A pharmacy permit holder, pharmacist, or practitioner who knowingly discloses [1]or uses[1] prescription monitoring information in violation of the provisions of sections 25 through [2]**[**29**]** 30[2] of P.L. , c. (C.) (pending before the Legislature as this bill), shall also be subject to disciplinary action pursuant to section 8 of P.L.1978, c.73 (C.45:1-21).

c. A penalty imposed under this section shall be collected by the director pursuant to the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.).

[2]**[**29.**]** 30.[2] (New section) Authority to contract. The division may contract with one or more vendors to establish and maintain the Prescription Monitoring Program pursuant to guidelines established by the director.

[2]**[**30.**]** 31.[2] Pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), the Director of the Division

of Consumer Affairs shall adopt rules and regulations necessary to effectuate the purposes of sections 24 through [2]**[**29**]** 30[2] of P.L. , c. (C.)(pending before the Legislature as this bill).

[2]**[**31.**]** 32.[2] (New section) Continuation of regulations. Orders, rules and regulations concerning implementation of P.L.1970, c.226 (C.24:21-1 et seq.), as amended and supplemented, issued or promulgated by the Department of Health and Senior Services prior to the effective date of P.L. , c. (C.)(pending before the Legislature as this bill), shall continue with full force and effect until amended or repealed by the Division of Consumer Affairs pursuant to law.

[2]**[**32.**]** 33.[2] The following section is repealed:
Section 41 of P.L.1970, c. 226 (C.24:21-41).

[2]**[**33.**]** 34.[2] Sections 1 through 23 and [2]**[**30**]** 31[2] through [2]**[**32**]** [3]**[**33[2]**]** 34[3]of this act shall take effect upon enactment, [3]provided however that section 22 shall remain inoperative until May 23, 2008,[3] and sections 24 through [2]**[**29**]** 30[2] shall take effect on the first day of the 19th month after the date of enactment. The Director of the Division of Consumer Affairs may take such anticipatory administrative action in advance thereof as shall be necessary for the implementation of this act.

Establishes Prescription Monitoring Program in Division of Consumer Affairs and provides division with authority over registration and control of controlled dangerous substances.

SENATE, No. 1604

STATE OF NEW JERSEY

212th LEGISLATURE

INTRODUCED MARCH 6, 2006

Sponsored by:
Senator RONALD L. RICE
District 28 (Essex)

SYNOPSIS

Establishes Prescription Monitoring Program in Division of Consumer Affairs.

CURRENT VERSION OF TEXT

As introduced.

AN ACT establishing a prescription monitoring program and supplementing Title 45 of the Revised Statutes.

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

1. As used in this act:

"Controlled dangerous substance" means any substance that is listed in Schedules II, III, IV and V of the schedules provided under the "New Jersey Controlled Dangerous Substances Act," P.L.1970, c.226 (C.24:21-1 et seq.).

"Director" means the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

"Division" means the Division of Consumer Affairs in the Department of Law and Public Safety.

"Practitioner" means an individual currently licensed, registered or otherwise authorized by the State to prescribe drugs in the course of professional practice.

"Program" means the Prescription Monitoring Program established under section 2 of this act.

2. a. There is established in the Division of Consumer Affairs in the Department of Law and Public Safety a Prescription Monitoring Program, which shall consist of an electronic system for monitoring controlled dangerous substances that are dispensed in the State by a pharmacist in an outpatient setting.

b. Each pharmacy permit holder shall submit to the division, by electronic means, at such intervals as are specified by the director, information about each prescription for a controlled dangerous substance dispensed by the pharmacy that includes:

(1) The surname and the first name of the patient for whom the medication is intended;

(2) The street address and telephone number of the patient;

(3) The original or refill date that the medication is dispensed and the initials of the dispensing pharmacist, if those initials and date are not recorded on the original prescription or in any other record approved by the New Jersey State Board of Pharmacy;

(4) The number or designation identifying the prescription and the National Drug Code of the drug dispensed;

(5) The prescribing practitioner's name, license number and Drug Enforcement Administration registration number;

(6) The name, strength and quantity of the drug dispensed;

(7) Any additional comments relevant to the patient's drug use, which may include any failure to accept the pharmacist's offer to counsel;

(8) the date that the prescription was issued by the practitioner; and

(9) such other information as the director determines necessary.

The pharmacy permit holder shall submit the information to the division no less than 30 days after dispensing the prescription, or according to a schedule to be determined by the director.

c. The division may grant a waiver of electronic submission to any pharmacy permit holder for good cause, including financial hardship, as determined by the director. The waiver shall state the format in which the pharmacy permit holder shall submit the required information.

d. The requirements of this act shall not apply to the dispensing of controlled dangerous substances to inpatients in a hospital or long-term care facility or at the time of discharge from the hospital or facility.

3. a. The division shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted and maintained is not disclosed, except as permitted in subsections c. and d. of this section.

b. The prescription monitoring information submitted to the division shall be confidential and not be subject to public disclosure under P.L.1963, c.73 (C.47:1A-1 et seq.), or P.L.2001, c.404 (C.47:1A-5 et al.).

c. The division shall review the prescription monitoring information provided by a pharmacy permit holder pursuant to this act. If there is reasonable cause to believe that a violation of law or regulations, or a breach of professional standards, may have occurred, the division shall notify the appropriate law enforcement agency and professional licensing board, and provide prescription monitoring information required for an investigation.

d. The division may provide prescription monitoring information to the following persons:

(1) a practitioner authorized to prescribe, dispense or administer controlled dangerous substances who certifies that the request is for the purpose of providing health care to a current patient of the practitioner. Nothing in this act shall be construed to require or obligate a practitioner to access or check the prescription monitoring information prior to prescribing, dispensing or administering medications or as part of the practitioner's professional practice;

(2) a pharmacist authorized to dispense controlled dangerous substances who certifies that the request is for the purpose of providing health care to a current patient. Nothing in this act shall be construed to require or obligate a pharmacist to access or check the prescription monitoring information prior to dispensing medications or as part of the pharmacist's professional practice;

(3) a designated representative of the State Board of Medical Examiners, New Jersey State Board of Dentistry, New Jersey Board of Nursing, New Jersey State Board of Pharmacy or State Board of

Veterinary Medical Examiners, as applicable, who certifies that he is engaged in a bona fide specific investigation of a designated practitioner whose professional practice was or is regulated by that board;

(4) a State, federal or municipal law enforcement officer who is acting pursuant to a court order and certifies that the officer is engaged in a bona fide specific investigation of a designated practitioner or patient;

(5) a designated representative of a State Medicaid program who certifies that he is engaged in a bona fide investigation of a designated practitioner or patient;

(6) a properly convened grand jury pursuant to a subpoena properly issued for the records; and

(7) authorized personnel of the division or vendor or contractor responsible for establishing and maintaining the program.

e. The director may provide nonidentifying prescription drug monitoring information to public or private entities for statistical, research or educational purposes.

4. The division shall be immune from civil liability arising from inaccuracy of any of the information submitted to it pursuant to this act.

5. a. A pharmacy permit holder who (1) knowingly fails to report data as required by this act, or (2) discloses data to a person or entity in violation of section 3 of this act shall be subject to disciplinary action pursuant to section 8 of P.L.1978, c.73 (C.45:1-21) and to a civil penalty in an amount not to exceed $1,000.

b. A person or other entity other than a pharmacy permit holder who knowingly discloses data to a person or entity in violation of section 3 of this act shall be subject to a civil penalty in an amount not to exceed $10,000.

c. A penalty imposed under this section shall be collected by the director pursuant to the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.).

6. The division may contract with one or more vendors to establish and maintain the Prescription Monitoring Program pursuant to guidelines established by the director.

7. There is created in the Department of the Treasury a nonlapsing fund to be known as the "Prescription Drug Monitoring Program Fund." The fund shall be the depository for penalties collected pursuant to section 5 of this act. Monies deposited into the fund and the interest earned thereon shall be used for the operation and administration of the Prescription Monitoring Program established pursuant to this act.

8. Pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), the Director of the Division of Consumer Affairs shall adopt rules and regulations necessary to implement the provisions of this act.

9. This act shall take effect 18 months after enactment, but the Director of the Division of Consumer Affairs may take such anticipatory administrative action in advance as shall be necessary for the implementation of the act.

STATEMENT

This bill establishes a Prescription Monitoring Program in the Division of Consumer Affairs (DCA) in the Department of Law and Public Safety, which is to consist of an electronic system for monitoring any controlled dangerous substance dispensed in New Jersey by a pharmacist in an outpatient setting.

Specifically, the bill provides as follows:

- Pharmacy permit holders (with the exception of those dispensing to inpatients or to patients at the time of discharge from a hospital) are required to forward to DCA, via an electronic system, certain information regarding prescribed controlled dangerous substances so that DCA can identify the diversion of prescription drugs. DCA may grant a waiver of electronic submission to a pharmacy permit holder for good cause and provide an alternative format for submitting the information. (Pharmacists are already required under N.J.S.A.45:14-68 to maintain patient profile information; and the electronic system for the Prescription Monitoring Program is based on the same information, adding only the date on which the prescription was dispensed by the practitioner, the National Drug Code for the dispensed drug and the practitioner's license and federal Drug Enforcement Administration registration numbers.) The information is to be submitted to DCA within 30 days after the prescription is dispensed, unless the Director of DCA specifies otherwise.
- DCA is to: review the prescription monitoring information provided by a pharmacy permit holder pursuant to the bill; and, if there is reasonable cause to believe a violation of law or regulations, or a breach of professional standards, may have occurred, notify the appropriate law enforcement agency and professional licensing board, and provide prescription information required for an investigation.
- DCA may provide limited prescription information to: a licensed practitioner or pharmacist regarding a current or prospective patient; a State, federal or municipal law enforcement officer acting pursuant to a court order and engaged

in a bona fide specific investigation of a designated practitioner or patient; a designated State Medicaid program representative engaged in a bona fide specific investigation of a designated practitioner or patient; a properly convened grand jury pursuant to a properly issued subpoena; and DCA personnel or vendors responsible for establishing and maintaining the program. The program information submitted to DCA is otherwise confidential and not subject to public disclosure under N.J.S.A.47:1A-1 et seq. or N.J.S.A.47:1A-5 et al. The director may, however, provide information for statistical, research and educational purposes if the information cannot be used to identify an individual patient.

- DCA is immune from civil liability arising from inaccuracy of any of the information submitted to it pursuant to the bill.
- A pharmacy permit holder who knowingly fails to submit prescription monitoring information to DCA or discloses data in violation of the bill is subject to disciplinary action and a fine of up to $1,000. A person or entity other than a pharmacy permit holder who knowingly discloses data in violation of the bill is subject to a fine of up to $10,000.
- A fund to be known as the "Prescription Drug Monitoring Program Fund" is created in the Department of the Treasury, into which fines and penalties collected for violations are to be deposited and used for the operation and administration of the program.
- The bill takes effect 18 months after enactment, but authorizes the Director of DCA to take anticipatory administrative action in advance as necessary for its implementation.

ASSEMBLY APPROPRIATIONS COMMITTEE

STATEMENT TO

[Second Reprint]

SENATE COMMITTEE SUBSTITUTE

SENATE, No. 1604

with committee amendments

STATE OF NEW JERSEY

DATED: JUNE 14, 2007

The Assembly Appropriations Committee reports favorably Senate Bill No. 1604 SCS (2R), with committee amendments.

The bill, as amended, establishes a Prescription Monitoring Program in the Division of Consumer Affairs to monitor controlled dangerous substances dispensed in most outpatient settings, and amends the "New Jersey Controlled Dangerous Substances Act," N.J.S.A. 24:21-1 et seq., to provide the division with statutory authority to administer all provisions of that law and the Prescription Monitoring Program. The Division of Consumer Affairs has been carrying out its registration and enforcement functions since 1993 pursuant to a memorandum of understanding with the Department of Health and Senior Services.

Under the Prescription Monitoring Program, at least every 30 days or according to a different schedule if federal law otherwise requires, pharmacy permit holders are required to provide the division with information electronically, unless the division waives the electronic submission requirement for good cause.

The bill requires the division to maintain procedures to protect patient privacy and confidentiality, including a password-protected system. The prescription monitoring information submitted to the division is to be confidential and not subject to public disclosure; however, the bill allows the director to provide non-identifying prescription drug monitoring information to public or private entities for statistical, research or educational purposes.

If the division determines that a violation of law may have occurred, the bill requires the division to notify the appropriate law enforcement agency or professional licensing board and provide the prescription monitoring information required for an investigation.

Under the bill, the division is immune from civil liability arising from inaccuracy of any of the information submitted to it, and a

pharmacy, pharmacist or practitioner is immune from civil liability arising from compliance with the Prescription Monitoring Program.

The bill provides penalties for violations of its provisions. A pharmacy permit holder, or a person designated by a pharmacy permit holder to report data, who knowingly fails to report data as required, is subject to disciplinary action and may be subject to a civil penalty up to $1,000 for repeated failure to comply with the Prescription Monitoring Program. Knowing disclosure or use of prescription monitoring information in violation of the program could result in a civil penalty up to $10,000, and, for pharmacy permit holders, pharmacists, and practitioners, disciplinary action by their respective licensing boards.

The bill establishes the "Controlled Dangerous Substances Administration and Enforcement Fund" as the depository for fees, cost recoveries and penalties collected in connection with the "New Jersey Controlled Dangerous Substances Act" and the Prescription Monitoring Program. The bill dedicates the balance of the fund to the collection of information, administration and enforcement of laws relating to controlled dangerous substances.

The bill authorizes the division to contract with one or more vendors to establish and maintain the Prescription Monitoring Program.

The amendments made by the bill to the "New Jersey Controlled Dangerous Substances Act" take effect upon its enactment, while the provisions establishing the Prescription Monitoring Program take effect on the first day of the 19th month after enactment.

As amended and reported by the committee, this bill is identical to Assembly Bill No. 1624 ACS as also amended and reported by the committee.

FISCAL IMPACT:

The Department of Law and Public Safety estimates implementing the provisions of this bill will cost $554,000 in the first year after enactment. These costs are attributable to salaries and benefits and to data processing costs. After adjustment for inflation and deduction of certain fixed costs, the division estimates the cost of this bill at $567,000 and $578,000 in the second and third years, respectively. These expenses could be higher, according to the Office of Legislative Services, if the Division of Consumer Affairs contracts with an outside vendor for implementation and maintenance.

New Jersey received a federal grant of $350,000 under the Harold Rogers Prescription Monitoring Program to operate a prescription monitoring program, which will offset first year costs. Federal money is also available through the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) for states with qualifying monitoring programs through State application.

It is not known to what extent program costs will be offset by the fines, penalties and fees established under the program.

COMMITTEE AMENDMENTS:

The amendments delay the operative date of section 22 of the bill. That section establishes new requirements for prescription blanks. The delay until May 23, 2008, which is the time by which federal rules require the use of national provider identifiers, will allow for the consumption of existing prescription blanks and the printing of the new format prescription blanks.

SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

STATEMENT TO

SENATE COMMITTEE SUBSTITUTE FOR
SENATE, No. 1604

STATE OF NEW JERSEY

DATED: DECEMBER 14, 2006

The Senate Health, Human Services and Senior Citizens Committee reports favorably a Senate Committee Substitute for Senate Bill No. 1604.

This committee substitute establishes a Prescription Monitoring Program in the Division of Consumer Affairs (DCA) in the Department of Law and Public Safety to monitor controlled dangerous substances dispensed in most outpatient settings in the State, and amends the "New Jersey Controlled Dangerous Substances Act" (N.J.S.A. 24:21-1 et seq.), so that DCA has statutory authority to administer all provisions of the act and the Prescription Monitoring Program. Although DHSS has statutory authority to administer the Controlled Dangerous Substances Act, DCA has been carrying out all its registration and enforcement functions since 1993 pursuant to a memorandum of understanding.

New Jersey received a federal grant of $350,000 under the Harold Rogers Prescription Monitoring Program, which requires that a state have a law requiring submission of prescription data to a centralized database administered by an authorized state agency. Federal money is also available through the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) for states with monitoring programs that meet federal requirements.

Sections 1 through 22 of this substitute amend the "New Jersey Controlled Dangerous Substances Act to authorize DCA to administer the provisions of the act. In addition, the definition of "official written order" is amended to allow for electronic prescriptions, and prescription blanks will be required to have the National Provider Identifier in applicable cases. Section 23 establishes in the Department of the Treasury a special, dedicated nonlapsing "Controlled Dangerous Substances Administration and Enforcement Fund" for fees, cost recoveries and penalties collected in connection with the "New Jersey Controlled Dangerous Substances Act" the Prescription Monitoring Program.

Sections 24 through 31 establish the Prescription Monitoring Program. Under the program, pharmacy permit holders are required

to provide DCA with information that will enable DCA to identify the diversion of prescription drugs. This program does not apply when drugs are dispensed to patients at the time of discharge from a hospital, or when drugs are directly administered to the patient.

Permit holders are required to forward the following information to DCA via an electronic system, unless DCA waives the electronic submission requirement for good cause:

-- the patient's name, date of birth, address and telephone number;

-- the date that the medication is dispensed;

-- the number or designation identifying the prescription and the National Drug Code of the drug dispensed;

-- the pharmacy permit number of the dispensing pharmacy;

-- the prescribing practitioner's name and Drug Enforcement Administration registration number;

-- the name, strength and quantity of the drug dispensed, number of refills ordered, and whether the drug was dispensed as a refill or a new prescription;

-- the date that the prescription was issued by the practitioner; and

-- such other information that is not inconsistent with federal law, regulation or funding eligibility requirements, as the Director of Consumer Affairs determines necessary.

The pharmacy permit holder shall submit the information to the division at least every 30 days, or according to a schedule if DCA determines that federal law otherwise requires.

DCA shall maintain procedures to protect patient privacy and confidentiality, and the information submitted to the division shall be confidential and not subject to public disclosure under N.J.S.A.47:1A-1 et seq., or N.J.S.A.47:1A-5 et al.

DCA shall review the prescription monitoring information and if it determines that a violation of law or regulations, or a breach of the applicable standards of practice, may have occurred, it shall notify the appropriate law enforcement agency or professional licensing board, and provide the prescription monitoring information required for an investigation.

DCA is authorized to provide prescription monitoring information to the following persons:

-- a practitioner authorized to prescribe, dispense or administer controlled dangerous substances who certifies that the request is for the purpose of providing health care to a current patient;

-- a pharmacist authorized to dispense controlled dangerous substances who certifies that the request is for the purpose of providing health care to a current patient;

-- a designated representative of the State Board of Medical Examiners, New Jersey State Board of Dentistry, New Jersey Board of Nursing, New Jersey State Board of Optometrists, New Jersey State Board of Pharmacy, State Board of Veterinary Medical Examiners, or any other board in this State or another state that regulates the practice

of persons who are authorized to prescribe or dispense controlled dangerous substances. The designated representative must certify that he is engaged in a bona fide specific investigation of a designated practitioner whose practice was or is regulated by that board;

-- a State, federal or municipal law enforcement officer who is acting pursuant to a court order and certifies that the officer is engaged in a bona fide specific investigation of a designated practitioner or patient;

-- a designated representative of a state Medicaid or other program who certifies that he is engaged in a bona fide investigation of a designated practitioner or patient;

-- a properly convened grand jury pursuant to a properly issued subpoena;

-- authorized DCA personnel or a vendor or contractor responsible for establishing and maintaining the program; and

-- a prescription monitoring program in another state with which the division has established an interoperability agreement.

The director of DCA may provide nonidentifying prescription drug monitoring information to public or private entities for statistical, research or educational purposes.

The substitute also provides DCA with immunity from civil liability arising from inaccuracy of any of the information submitted to it, and a pharmacy, pharmacist or practitioner shall be immune from civil liability arising from compliance with the program.

A pharmacy permit holder, or a person designated by a pharmacy permit holder to report data, who knowingly fails to report data as required, shall be subject to disciplinary action, and may be subject to a civil penalty in an amount not to exceed $1,000 for repeated failure to comply with the Prescription Monitoring Program. A pharmacy permit holder, pharmacist or practitioner, or any other person or entity who knowingly discloses prescription monitoring information in violation of the provisions of the Prescription Monitoring Program shall be subject to a civil penalty in an amount not to exceed $10,000, and, in the case of a pharmacy permit holder, pharmacist, or practitioner, disciplinary action pursuant to N.J.S.A. 45:1-21.

The substitute authorizes DCA to contract with one or more vendors to establish and maintain the program.

The amendments to the “New Jersey Controlled Dangerous Substances Act” shall take effect upon enactment, and the provisions establishing the Prescription Monitoring Program shall take effect on the first day of the 19th month after the date of enactment.

SENATE BUDGET AND APPROPRIATIONS COMMITTEE

STATEMENT TO

SENATE COMMITTEE SUBSTITUTE FOR
SENATE, No. 1604

with committee amendments

STATE OF NEW JERSEY

DATED: JANUARY 29, 2007

The Senate Budget and Appropriations Committee reports favorably the Senate Committee Substitute for Senate Bill No. 1604 (SCS), with committee amendments.

The committee substitute establishes a Prescription Monitoring Program in the Division of Consumer Affairs to monitor controlled dangerous substances dispensed in most outpatient settings, and amends the "New Jersey Controlled Dangerous Substances Act," N.J.S.A. 24:21-1 et seq., to provide the division with statutory authority to administer all provisions of that law and the Prescription Monitoring Program. The Division of Consumer Affairs has been carrying out its registration and enforcement functions since 1993 pursuant to a memorandum of understanding with the Department of Health and Senior Services.

Under the Prescription Monitoring Program, at least every 30 days or according to a different schedule if federal law otherwise requires, pharmacy permit holders are required to provide the division with information electronically, unless the division waives the electronic submission requirement for good cause.

The division is to maintain procedures to protect patient privacy and confidentiality, including a password-protected system. The prescription monitoring information submitted to the division is to be confidential and not subject to public disclosure; however, it may provide non-identifying prescription drug monitoring information to public or private entities for statistical, research or educational purposes.

If the division determines that a violation of law may have occurred, it is to notify the appropriate law enforcement agency or professional licensing board and provide the prescription monitoring information required for an investigation.

The division is immune from civil liability arising from inaccuracy of any of the information submitted to it, and a pharmacy, pharmacist or practitioner is immune from civil liability arising from compliance with the Prescription Monitoring Program.

A pharmacy permit holder, or a person designated by a pharmacy permit holder to report data, who knowingly fails to report data as required, is subject to disciplinary action and may be subject to a civil penalty up to $1,000 for repeated failure to comply with the Prescription Monitoring Program. Knowing disclosure or use of prescription monitoring information in violation of the program could result in a civil penalty up to $10,000, and, for pharmacy permit holders, pharmacists, and practitioners, disciplinary action by their respective licensing boards.

The substitute establishes in the Department of the Treasury a special, dedicated nonlapsing "Controlled Dangerous Substances Administration and Enforcement Fund" as the depository for fees, cost recoveries and penalties collected in connection with the "New Jersey Controlled Dangerous Substances Act" and the Prescription Monitoring Program.

The division may contract with one or more vendors to establish and maintain the Prescription Monitoring Program.

The amendments to the "New Jersey Controlled Dangerous Substances Act" would take effect upon enactment, while the provisions establishing the Prescription Monitoring Program take effect on the first day of the 19th month after the date of enactment.

COMMITTEE AMENDMENTS:

The committee amendments:

- Provide that the source of payment for the drug dispensed will be required information under the program (section 25).
- Add measures to protect patient privacy through the establishment of a password-protected system and through a requirement that individuals accessing program information online affirm their intent to comply with program requirements and provide a reason for accessing program information. In addition, the division is to offer an on-line tutorial for those persons authorized to obtain prescription monitoring information which would address how to access the information, the rights and responsibilities of persons who are the subject of or who access the information, and a summary of the federal health privacy rule (45 CFR Parts 160 and 164) along with a link to the federal Department of Health and Human Services website (section 26).
- Allow for the assessment of civil penalties for the use of information obtained through the prescription monitoring program in violation of the purposes of the provisions of the substitute.

FISCAL IMPACT:

The Department of Law and Public Safety estimates implementing the provisions of this substitute will cost $554,000 in the first year of enactment. These costs are attributable to salaries and

benefits and data processing. After adjustment for inflation and deduction of certain fixed costs, the division estimates the cost of this bill at $567,000 and $578,000, in the second and third years, respectively. These expenses could be higher, according to the OLS, if the Division of Consumer Affairs contracts with an outside vendor for implementation and maintenance.

New Jersey received a federal grant of $350,000 under the Harold Rogers Prescription Monitoring Program to operate a prescription monitoring program which will offset first year costs. Federal money is also available through the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) for states with qualifying monitoring programs through State application.

It is not known to what extent program costs will be offset by the fines, penalties and fees established under the program.

STATEMENT TO

[First Reprint]

SENATE COMMITTEE SUBSTITUTE FOR

SENATE, No. 1604

with Senate Floor Amendments
(Proposed By Senator RICE)

ADOPTED: FEBRUARY 22, 2007

This Senate floor amendment adds a new section 27, which authorizes the Director of the Division of Consumer Affairs to adopt a regulation to expand the Prescription Monitoring Program to include information about prescription drugs that are not controlled dangerous substances, but which the director determines should be monitored.

The criteria to be considered by the director include: the actual or relative potential for abuse; scientific evidence of its pharmacological effect, if known; the state of current scientific knowledge regarding the drug; its history and current pattern of abuse; the scope, duration and significance of abuse; what, if any, risk to the public health; and its psychic or physiological dependence liability.

At the time the notice to expand the program is published in the New Jersey Register, the director shall provide a copy of the notice of proposed rule making to the chairpersons of the standing legislative reference committees on health of the Senate and General Assembly.

Other amendments are technical and renumber the sections to reflect the addition of the new section.

LEGISLATIVE FISCAL ESTIMATE

SENATE COMMITTEE SUBSTITUTE FOR

SENATE, No. 1604

STATE OF NEW JERSEY
212th LEGISLATURE

DATED: FEBRUARY 13, 2007

SUMMARY

Synopsis:	Establishes Prescription Monitoring Program in Division of Consumer Affairs.
Type of Impact:	Minimal Increased Expenditure. Controlled Dangerous Substances Administration and Enforcement Fund and General Fund.
Agencies Affected:	Department of Law and Public Safety; Division of Consumer Affairs. Department of Treasury

Office of Legislative Services Estimate

Fiscal Impact	Year 1	Year 2	Year 3
State Cost	$554,000	$567,000	$578,000
State Revenue	$350,000	Indeterminate - See Comments Below	

- The Office of Legislative Services (OLS) **concurs** with the informal Executive estimate if the Division of Consumer Affairs implements the program. If Division of Consumer Affairs determines to contract with an outside vendor for implementation and/or maintenance, OLS estimates the cost of the program will vary. The OLS notes that the State received a $350,000 federal grant in FFY 2004 to implement this program. Funding for future years is indeterminate and depends on the fees set by the Director of Division of Consumer Affairs to offset the monitoring service as well as fines and penalties collected from non-compliance. Additional federal funds may also become available through State application.

- Establishes Prescription Monitoring Program in Division of Consumer Affairs within the Department of Law and Public Safety to monitor controlled dangerous substances dispensed in New Jersey by a pharmacist.

- Creates the "Controlled Dangerous Substances Administration and Enforcement Fund" within the Department of the Treasury for fees, cost recoveries and penalties associated with this program.

- Requires the Legislature to annually appropriate money from the enforcement fund for expenses related to the collection of information, administrative and enforcement.

- Allows the Division of Consumer Affairs to contract with an outside vendor to establish and maintain the program.

- Provides an effective date and authorizes the Director of Division of Consumer Affairs to take any administrative action necessary in advance for the implementation of the bill.

BILL DESCRIPTION

Senate Committee Substitute for Senate Bill No. 1604 of 2006 establishes a Prescription Monitoring Program in the Division of Consumer Affairs in the Department of Law and Public Safety. This program will monitoring controlled dangerous substance dispensed in New Jersey by a pharmacist.

This bill requires that pharmacy permit holders supply the division with certain information regarding prescribed controlled dangerous substances so that the division may identify the diversion of prescription drugs and request that the information be submitted to the division within 30 days after the prescription is dispensed.

The bill requires the division to review the prescription monitoring information provided by a pharmacy permit holder and, if there is reasonable cause to believe a violation of law or regulations or a breach of professional standards may have occurred, notify the appropriate law enforcement agency and professional licensing board, and provide prescription information required for an investigation.

The bill provides immunity to the division, pharmacy permit holder, pharmacist, or practitioner from civil liability arising from inaccuracy of any of the information submitted.

The bill establishes penalties for a pharmacy permit holder, or person designated by the holder, who knowingly fails to submit prescription monitoring information to the division or discloses data. They are subject to disciplinary action and a fine of up to $1,000. A person or entity other than a pharmacy permit holder who knowingly discloses data is subject to a fine of up to $10,000.

A fund to be known as the “Controlled Dangerous Substances Administration and Enforcement Fund” is established within the Department of the Treasury to collect fees, cost recoveries and penalties associated with this program. This fund will be used to pay for the establishment and maintenance of the program.

The bill provides an effective date of 18 months after enactment, but authorizes the Director of the division to take anticipatory administrative action in advance as necessary for its implementation.

FISCAL ANALYSIS

EXECUTIVE BRANCH

The Department of Law and Public Safety informally estimates the cost of implementing the provisions of this bill at $554,000 in the first year of enactment. This amount includes $278,000 in salaries and benefits for a program manager, program technician and two full-time investigators; materials and supplies, at $3,000; and $273,000 for services other than personnel, specifically data processing.

After adjustment for inflation and deduction of certain fixed costs, the division estimates the cost of this bill at $567,000 and $578,000, in the second and third years, respectively.

The division further noted that any initial expenses will be funded by a FFY 2004 one-time Prescription Monitoring grant of $350,000. This federal grant was provided to the State to establish a prescription monitoring program and should cover the start up and discovery costs of running data.

OFFICE OF LEGISLATIVE SERVICES

The OLS concurs with the informal Executive estimate if the Division of Consumer Affairs implements the program. If Division of Consumer Affairs determines to contract with an outside vendor, however, for the implementation and/or maintenance, OLS estimates the cost of the program will increase.

In the first year $350,000 from a 2004 federal grant awarded under the Harold Rogers Prescription Monitoring Program will be provided to Division of Consumer Affairs. Additional federal funds may also become available through State application. Funding for future years is indeterminate and depends on the fees set by the Director of Division of Consumer Affairs to offset the monitoring service as well as fines and penalties collected from non-compliance.

Section:	*Law and Public Safety*
Analyst:	*Kristin A. Brunner* *Associate Fiscal Analyst*
Approved:	*David J. Rosen* *Legislative Budget and Finance Officer*

This fiscal estimate has been prepared pursuant to P.L. 1980, c.67.

ASSEMBLY, No. 1624

STATE OF NEW JERSEY

212th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2006 SESSION

Sponsored by:
Assemblyman HERB CONAWAY, JR.
District 7 (Burlington and Camden)

SYNOPSIS

Establishes Prescription Monitoring Program in Division of Consumer Affairs.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel

AN ACT establishing a prescription monitoring program and supplementing Title 45 of the Revised Statutes.

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

1. As used in this act:

"Controlled dangerous substance" means any substance that is listed in Schedules II, III, IV and V of the schedules provided under the "New Jersey Controlled Dangerous Substances Act," P.L.1970, c.226 (C.24:21-1 et seq.).

"Director" means the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

"Division" means the Division of Consumer Affairs in the Department of Law and Public Safety.

"Practitioner" means an individual currently licensed, registered or otherwise authorized by the State to prescribe drugs in the course of professional practice.

"Program" means the Prescription Monitoring Program established under section 2 of this act.

2. a. There is established in the Division of Consumer Affairs in the Department of Law and Public Safety a Prescription Monitoring Program, which shall consist of an electronic system for monitoring controlled dangerous substances that are dispensed in the State by a pharmacist in an outpatient setting.

b. Each pharmacy permit holder shall submit to the division, by electronic means, at such intervals as are specified by the director, information about each prescription for a controlled dangerous substance dispensed by the pharmacy that includes:

(1) The surname and the first name of the patient for whom the medication is intended;

(2) The street address and telephone number of the patient;

(3) The original or refill date that the medication is dispensed and the initials of the dispensing pharmacist, if those initials and date are not recorded on the original prescription or in any other record approved by the New Jersey State Board of Pharmacy;

(4) The number or designation identifying the prescription and the National Drug Code of the drug dispensed;

(5) The prescribing practitioner's name, license number and Drug Enforcement Administration registration number;

(6) The name, strength and quantity of the drug dispensed;

(7) Any additional comments relevant to the patient's drug use, which may include any failure to accept the pharmacist's offer to counsel;

(8) the date that the prescription was issued by the practitioner; and

(9) such other information as the director determines necessary.

The pharmacy permit holder shall submit the information to the division no less than 30 days after dispensing the prescription, or according to a schedule to be determined by the director.

c. The division may grant a waiver of electronic submission to any pharmacy permit holder for good cause, including financial hardship, as determined by the director. The waiver shall state the format in which the pharmacy permit holder shall submit the required information.

d. The requirements of this act shall not apply to the dispensing of controlled dangerous substances to inpatients in a hospital or long-term care facility or at the time of discharge from the hospital or facility.

3. a. The division shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted and maintained is not disclosed, except as permitted in subsections c. and d. of this section.

b. The prescription monitoring information submitted to the division shall be confidential and not be subject to public disclosure under P.L.1963, c.73 (C.47:1A-1 et seq.), or P.L.2001, c.404 (C.47:1A-5 et al.).

c. The division shall review the prescription monitoring information provided by a pharmacy permit holder pursuant to this act. If there is reasonable cause to believe that a violation of law or regulations, or a breach of professional standards, may have occurred, the division shall notify the appropriate law enforcement agency and professional licensing board, and provide prescription monitoring information required for an investigation.

d. The division may provide prescription monitoring information to the following persons:

(1) a practitioner authorized to prescribe, dispense or administer controlled dangerous substances who certifies that the request is for the purpose of providing health care to a current patient of the practitioner. Nothing in this act shall be construed to require or obligate a practitioner to access or check the prescription monitoring information prior to prescribing, dispensing or administering medications or as part of the practitioner's professional practice;

(2) a pharmacist authorized to dispense controlled dangerous substances who certifies that the request is for the purpose of providing health care to a current patient. Nothing in this act shall be construed to require or obligate a pharmacist to access or check the prescription monitoring information prior to dispensing medications or as part of the pharmacist's professional practice;

(3) a designated representative of the State Board of Medical Examiners, New Jersey State Board of Dentistry, New Jersey Board of Nursing, New Jersey State Board of Pharmacy or State Board of Veterinary Medical Examiners, as applicable, who certifies that he

is engaged in a bona fide specific investigation of a designated practitioner whose professional practice was or is regulated by that board;

(4) a State, federal or municipal law enforcement officer who is acting pursuant to a court order and certifies that the officer is engaged in a bona fide specific investigation of a designated practitioner or patient;

(5) a designated representative of a State Medicaid program who certifies that he is engaged in a bona fide investigation of a designated practitioner or patient;

(6) a properly convened grand jury pursuant to a subpoena properly issued for the records; and

(7) authorized personnel of the division or vendor or contractor responsible for establishing and maintaining the program.

e. The director may provide nonidentifying prescription drug monitoring information to public or private entities for statistical, research or educational purposes.

4. The division shall be immune from civil liability arising from inaccuracy of any of the information submitted to it pursuant to this act.

5. a. A pharmacy permit holder who (1) knowingly fails to report data as required by this act, or (2) discloses data to a person or entity in violation of section 3 of this act shall be subject to disciplinary action pursuant to section 8 of P.L.1978, c.73 (C.45:1-21) and to a civil penalty in an amount not to exceed $1,000.

b. A person or other entity other than a pharmacy permit holder who knowingly discloses data to a person or entity in violation of section 3 of this act shall be subject to a civil penalty in an amount not to exceed $10,000.

c. A penalty imposed under this section shall be collected by the director pursuant to the "Penalty Enforcement Law of 1999," P.L.1999, c.274 (C.2A:58-10 et seq.).

6. The division may contract with one or more vendors to establish and maintain the Prescription Monitoring Program pursuant to guidelines established by the director.

7. There is created in the Department of the Treasury a nonlapsing fund to be known as the "Prescription Drug Monitoring Program Fund." The fund shall be the depository for penalties collected pursuant to section 5 of this act. Monies deposited into the fund and the interest earned thereon shall be used for the operation and administration of the Prescription Monitoring Program established pursuant to this act.

8. Pursuant to the "Administrative Procedure Act," P.L.1968,

c.410 (C.52:14B-1 et seq.), the Director of the Division of Consumer Affairs shall adopt rules and regulations necessary to implement the provisions of this act.

9. This act shall take effect 18 months after enactment, but the Director of the Division of Consumer Affairs may take such anticipatory administrative action in advance as shall be necessary for the implementation of the act.

STATEMENT

This bill establishes a Prescription Monitoring Program in the Division of Consumer Affairs (DCA) in the Department of Law and Public Safety, which is to consist of an electronic system for monitoring any controlled dangerous substance dispensed in New Jersey by a pharmacist in an outpatient setting.

Specifically, the bill provides as follows:

- Pharmacy permit holders (with the exception of those dispensing to inpatients or to patients at the time of discharge from a hospital) are required to forward to DCA, via an electronic system, certain information regarding prescribed controlled dangerous substances so that DCA can identify the diversion of prescription drugs. DCA may grant a waiver of electronic submission to a pharmacy permit holder for good cause and provide an alternative format for submitting the information. (Pharmacists are already required under N.J.S.A.45:14-68 to maintain patient profile information; and the electronic system for the Prescription Monitoring Program is based on the same information, adding only the date on which the prescription was dispensed by the practitioner, the National Drug Code for the dispensed drug and the practitioner's license and federal Drug Enforcement Administration registration numbers.) The information is to be submitted to DCA within 30 days after the prescription is dispensed, unless the Director of DCA specifies otherwise.
- DCA is to: review the prescription monitoring information provided by a pharmacy permit holder pursuant to the substitute; and, if there is reasonable cause to believe a violation of law or regulations, or a breach of professional standards, may have occurred, notify the appropriate law enforcement agency and professional licensing board, and provide prescription information required for an investigation.
- DCA may provide limited prescription information to: a licensed practitioner or pharmacist regarding a current or

prospective patient; a State, federal or municipal law enforcement officer acting pursuant to a court order and engaged in a bona fide specific investigation of a designated practitioner or patient; a designated State Medicaid program representative engaged in a bona fide specific investigation of a designated practitioner or patient; a properly convened grand jury pursuant to a properly issued subpoena; and DCA personnel or vendors responsible for establishing and maintaining the program. The program information submitted to DCA is otherwise confidential and not subject to public disclosure under N.J.S.A.47:1A-1 et seq. or N.J.S.A.47:1A-5 et al. The director may, however, provide information for statistical, research and educational purposes if the information cannot be used to identify an individual patient.

- DCA is immune from civil liability arising from inaccuracy of any of the information submitted to it pursuant to the substitute.
- A pharmacy permit holder who knowingly fails to submit prescription monitoring information to DCA or discloses data in violation of the substitute is subject to disciplinary action and a fine of up to $1,000. A person or entity other than a pharmacy permit holder who knowingly discloses data in violation of the substitute is subject to a fine of up to $10,000.
- A fund to be known as the "Prescription Drug Monitoring Program Fund" is created in the Department of the Treasury, into which fines and penalties collected for violations are to be deposited and used for the operation and administration of the program.
- The bill takes effect 18 months after enactment, but authorizes the Director of DCA to take anticipatory administrative action in advance as necessary for its implementation.

ASSEMBLY HEALTH AND SENIOR SERVICES COMMITTEE

STATEMENT TO

ASSEMBLY COMMITTEE SUBSTITUTE FOR
ASSEMBLY, No. 1624

STATE OF NEW JERSEY

DATED: JANUARY 18, 2007

The Assembly Health and Senior Services Committee reports favorably an Assembly Committee Substitute for Assembly Bill No. 1624.

This committee substitute establishes a Prescription Monitoring Program in the Division of Consumer Affairs (DCA) in the Department of Law and Public Safety to monitor controlled dangerous substances dispensed in most outpatient settings in New Jersey, and amends the "New Jersey Controlled Dangerous Substances Act," P.L.1970, c.226 (C.24:21-1 et seq.), to provide DCA with statutory authority to administer all provisions of that law and the Prescription Monitoring Program. (Although the Department of Health and Senior Services has statutory authority to administer the law, DCA has been carrying out its registration and enforcement functions since 1993 pursuant to a memorandum of understanding between the two.)

New Jersey has received a federal grant of $350,000 under the Harold Rogers Prescription Monitoring Program, which requires that a state have a law requiring submission of prescription data to a centralized database administered by an authorized state agency; and federal money is also available through the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) for states with monitoring programs that meet federal requirements.

The substitute provides specifically as follows:

Amendments to "New Jersey Controlled Dangerous Substances Act"

- Sections 1 through 22 amend the "New Jersey Controlled Dangerous Substances Act" to authorize DCA to administer the provisions of that law.
- In addition, the definition of "official written order" is amended to allow for electronic prescriptions, and prescription blanks will be required to have the National Provider Identifier in applicable cases.

"Controlled Dangerous Substances Administration and Enforcement Fund"

- Section 23 establishes in the Department of the Treasury a special, dedicated nonlapsing "Controlled Dangerous Substances Administration and Enforcement Fund" as the depository for fees, cost recoveries and penalties collected in connection with the "New Jersey Controlled Dangerous Substances Act" and the Prescription Monitoring Program established under this substitute.
- The Legislature is to annually appropriate monies from the fund to DCA for the collection of information, administration, and enforcement of laws relating to controlled dangerous substances.

Establishment of Prescription Monitoring Program

- Sections 24 through 32 establish the Prescription Monitoring Program, under which pharmacy permit holders are required to provide DCA with information that will enable it to identify the diversion of prescription drugs. The program will not apply when drugs are dispensed to patients at the time of discharge from a hospital, or when drugs are directly administered to the patient.
- Permit holders are required to forward the following information to DCA electronically, unless DCA waives the electronic submission requirement for good cause:

-- the patient's name, date of birth, address and telephone number;

-- the date that the medication is dispensed;

-- the number or designation identifying the prescription and the National Drug Code of the drug dispensed;

-- the pharmacy permit number of the dispensing pharmacy;

-- the prescribing practitioner's name and Drug Enforcement Administration registration number;

-- the name, strength and quantity of the drug dispensed, number of refills ordered, and whether the drug was dispensed as a refill or a new prescription;

-- the date that the prescription was issued by the practitioner;

-- the source of payment for the drug dispensed; and

-- such other information that is not inconsistent with federal law, regulation or funding eligibility requirements, as the Director of DCA determines necessary.

- The pharmacy permit holder is to submit the required information to DCA at least every 30 days, or according to a schedule if DCA determines that federal law otherwise requires.
- DCA is to maintain procedures to protect patient privacy and confidentiality, including, but not limited to, the use of a password-protected system for maintaining this information and permitting access thereto as authorized under the substitute, and a requirement that a person to whom DCA may provide prescription monitoring

information must provide on-line affirmation of the person's intent to comply with the provisions of the substitute as a condition of accessing the information.

- The prescription monitoring information submitted to DCA is to be confidential and not subject to public disclosure under P.L.1963, c.73 (C.47:1A-1 et seq.) or P.L.2001, c.404 (C.47:1A-5 et al.).
- DCA is to review the prescription monitoring information and if it determines that a violation of law or regulations, or a breach of the applicable standards of practice, may have occurred, it is to notify the appropriate law enforcement agency or professional licensing board, and provide the prescription monitoring information required for an investigation.
- DCA is authorized to provide prescription monitoring information to the following persons:

-- a practitioner authorized to prescribe, dispense or administer controlled dangerous substances who certifies that the request is for the purpose of providing health care to a current patient;

-- a pharmacist authorized to dispense controlled dangerous substances who certifies that the request is for the purpose of providing health care to a current patient;

-- a designated representative of the State Board of Medical Examiners, New Jersey State Board of Dentistry, New Jersey Board of Nursing, New Jersey State Board of Optometrists, New Jersey State Board of Pharmacy, State Board of Veterinary Medical Examiners, or any other board in this or another state that regulates the practice of persons authorized to prescribe or dispense controlled dangerous substances, if the designated representative certifies that he is engaged in a bona fide specific investigation of a designated practitioner whose practice was or is regulated by that board;

-- a State, federal or municipal law enforcement officer who is acting pursuant to a court order and certifies that the officer is engaged in a bona fide specific investigation of a designated practitioner or patient;

-- a designated representative of a state Medicaid or other program who certifies that he is engaged in a bona fide investigation of a designated practitioner or patient;

-- a properly convened grand jury pursuant to a properly issued subpoena;

-- authorized DCA personnel or a vendor or contractor responsible for establishing and maintaining the program; and

-- a prescription monitoring program in another state with which DCA has established an interoperability agreement.

- A person authorized to obtain prescription monitoring information under the substitute, as a condition of obtaining this information, is required to certify, by means of entering an on-line statement in a form and manner prescribed by regulation of the Director of DCA, the reasons for seeking to obtain that information.

- DCA is to offer an on-line tutorial for those persons authorized to obtain prescription monitoring information under the substitute, which, at a minimum, includes: how to access prescription monitoring information; the rights and responsibilities of persons who are the subject of or access this information and the other provisions of the substitute and the regulations adopted pursuant thereto, regarding the permitted uses of that information and penalties for violations thereof; and a summary of the requirements of the federal health privacy rule (45 CFR Parts 160 and 164) and a hypertext link to the federal Department of Health and Human Services website for further information about the specific provisions of the privacy rule.
- The Director of DCA may provide nonidentifying prescription drug monitoring information to public or private entities for statistical, research or educational purposes.
- The substitute also provides DCA with immunity from civil liability arising from inaccuracy of any of the information submitted to it, and a pharmacy, pharmacist or practitioner is to be immune from civil liability arising from compliance with the Prescription Monitoring Program.
- A pharmacy permit holder, or a person designated by a pharmacy permit holder to report data, who knowingly fails to report data as required, is subject to disciplinary action, and may be subject to a civil penalty in an amount not to exceed $1,000 for repeated failure to comply with the Prescription Monitoring Program. A pharmacy permit holder, pharmacist or practitioner, or any other person or entity who knowingly discloses or uses prescription monitoring information in violation of the provisions of the Prescription Monitoring Program is liable to a civil penalty in an amount not to exceed $10,000, and, in the case of a pharmacy permit holder, pharmacist, or practitioner, disciplinary action pursuant to section 8 of P.L.1978, c.73 (C.45:1-21).
- The substitute authorizes DCA to contract with one or more vendors to establish and maintain the Prescription Monitoring Program.

Provisions for Expanding the Prescription Monitoring Program

- Section 27 authorizes the Director of DCA, beginning no sooner than one year after the Prescription Monitoring Program commences operations, to expand the program to include information about each prescription for a prescription drug that is not a controlled dangerous substance, if the Attorney General recommends to, or concurs with, the director in writing that the prescription drug should be monitored under the program, for such period of time as the Attorney General determines appropriate.
- The Attorney General is to notify the chairpersons of the standing legislative reference committees on health of the Senate and General

Assembly, no later than the 60th day prior to the expansion of the Prescription Monitoring Program, of the proposed expansion.

- The program expansion is to be effectuated by regulation of the director.

Repealer

The substitute repeals section 41 of P.L.1970, c.226 (C.24:21-41), which concerned the applicability of orders, rules and regulations that were in effect prior to the effective date of the "New Jersey Controlled Dangerous Substances Act."

Effective Dates

- The amendments to the "New Jersey Controlled Dangerous Substances Act" take effect upon enactment of the substitute.
- The provisions establishing the Prescription Monitoring Program take effect on the first day of the 19th month after the date of enactment, but the Director of DCA is authorized to take anticipatory administrative action in advance as necessary to implement the program.

This substitute is similar to Senate Bill No. 1604 (SCS) (Rice), which is currently pending in the Senate Budget and Appropriations Committee.

ASSEMBLY APPROPRIATIONS COMMITTEE

STATEMENT TO

ASSEMBLY COMMITTEE SUBSTITUTE FOR
ASSEMBLY, No. 1624

with committee amendments

STATE OF NEW JERSEY

DATED: JUNE 14, 2007

The Assembly Appropriations Committee reports favorably Assembly Bill No. 1624 (ACS), with committee amendments.

The bill, as amended, establishes a Prescription Monitoring Program in the Division of Consumer Affairs to monitor controlled dangerous substances dispensed in most outpatient settings, and amends the "New Jersey Controlled Dangerous Substances Act," N.J.S.A. 24:21-1 et seq., to provide the division with statutory authority to administer all provisions of that law and the Prescription Monitoring Program. The Division of Consumer Affairs has been carrying out its registration and enforcement functions since 1993 pursuant to a memorandum of understanding with the Department of Health and Senior Services.

Under the Prescription Monitoring Program, at least every 30 days or according to a different schedule if federal law otherwise requires, pharmacy permit holders are required to provide the division with information electronically, unless the division waives the electronic submission requirement for good cause.

The bill requires the division to maintain procedures to protect patient privacy and confidentiality, including a password-protected system. The prescription monitoring information submitted to the division is to be confidential and not subject to public disclosure; however, the bill allows the director to provide non-identifying prescription drug monitoring information to public or private entities for statistical, research or educational purposes.

If the division determines that a violation of law may have occurred, the bill requires the division to notify the appropriate law enforcement agency or professional licensing board and provide the prescription monitoring information required for an investigation.

Under the bill, the division is immune from civil liability arising from inaccuracy of any of the information submitted to it, and a pharmacy, pharmacist or practitioner is immune from civil liability arising from compliance with the Prescription Monitoring Program.

The bill provides penalties for violations of its provisions. A pharmacy permit holder, or a person designated by a pharmacy permit

holder to report data, who knowingly fails to report data as required, is subject to disciplinary action and may be subject to a civil penalty up to $1,000 for repeated failure to comply with the Prescription Monitoring Program. Knowing disclosure or use of prescription monitoring information in violation of the program could result in a civil penalty up to $10,000, and, for pharmacy permit holders, pharmacists, and practitioners, disciplinary action by their respective licensing boards.

The bill establishes the "Controlled Dangerous Substances Administration and Enforcement Fund" as the depository for fees, cost recoveries and penalties collected in connection with the "New Jersey Controlled Dangerous Substances Act" and the Prescription Monitoring Program. The bill dedicates the balance of the fund to the collection of information, administration and enforcement of laws relating to controlled dangerous substances.

The bill authorizes the division to contract with one or more vendors to establish and maintain the Prescription Monitoring Program.

The amendments made by the bill to the "New Jersey Controlled Dangerous Substances Act" take effect upon its enactment, while the provisions establishing the Prescription Monitoring Program take effect on the first day of the 19th month after enactment.

As amended and reported by the committee, this bill is identical to Senate Bill No. 1604 SCS (2R) as also amended and reported by the committee.

FISCAL IMPACT:

The Department of Law and Public Safety estimates implementing the provisions of this bill will cost $554,000 in the first year after enactment. These costs are attributable to salaries and benefits and to data processing costs. After adjustment for inflation and deduction of certain fixed costs, the division estimates the cost of this bill at $567,000 and $578,000 in the second and third years, respectively. These expenses could be higher, according to the Office of Legislative Services, if the Division of Consumer Affairs contracts with an outside vendor for implementation and maintenance.

New Jersey received a federal grant of $350,000 under the Harold Rogers Prescription Monitoring Program to operate a prescription monitoring program, which will offset first year costs. Federal money is also available through the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) for states with qualifying monitoring programs through State application.

It is not known to what extent program costs will be offset by the fines, penalties and fees established under the program.

COMMITTEE AMENDMENTS:

The amendments delay the operative date of section 22 of the bill. That section establishes new requirements for prescription blanks. The

delay until May 23, 2008, which is the time by which federal rules require the use of national provider identifiers, will allow for the consumption of existing prescription blanks and the printing of the new format prescription blanks.

STATEMENT TO

[First Reprint]

ASSEMBLY COMMITTEE SUBSTITUTE FOR

ASSEMBLY, No. 1624

with Assembly Floor Amendments
(Proposed By Assemblyman CONAWAY)

ADOPTED: JUNE 21, 2007

These amendments revise section 27 of the bill regarding expansion of the prescription monitoring program. The amendments provide that the Director of the Division of Consumer Affairs may adopt a regulation to expand the program to include prescription drugs that are not controlled dangerous substances. The amendments also set forth the process for determining whether a prescription drug should be monitored.

These amendments make this bill identical to S-1604 SCS (3R).

LEGISLATIVE FISCAL ESTIMATE

ASSEMBLY COMMITTEE SUBSTITUTE FOR

ASSEMBLY, No. 1624

STATE OF NEW JERSEY
212th LEGISLATURE

DATED: APRIL 23, 2007

SUMMARY

Synopsis:	Establishes Prescription Monitoring Program in DCA and provides DCA with authority over registration and control of controlled dangerous substances.
Type of Impact:	Minimal Increased Expenditure. Controlled Dangerous Substances Administration and Enforcement Fund and General Fund.
Agencies Affected:	Department of Law and Public Safety; Division of Consumer Affairs. Department of Treasury

Office of Legislative Services Estimate

Fiscal Impact	Year 1	Year 2	Year 3
State Cost	$554,000	$567,000	$578,000
State Revenue	$350,000	Indeterminate - See Comments Below	

- The Office of Legislative Services (OLS) **concurs** with the informal Executive estimate if the Division of Consumer Affairs implements the program. If Division of Consumer Affairs determines to contract with an outside vendor for implementation and/or maintenance, OLS estimates the cost of the program will vary. The OLS notes that the State received a $350,000 federal grant in FFY 2004 to implement this program. Funding for future years is indeterminate and depends on the fees set by the Director of Division of Consumer Affairs to offset the monitoring service as well as fines and penalties collected from non-compliance. Additional federal funds may also become available through State application.

- Establishes Prescription Monitoring Program in Division of Consumer Affairs within the Department of Law and Public Safety to monitor controlled dangerous substances dispensed in New Jersey by a pharmacist.

- Creates the "Controlled Dangerous Substances Administration and Enforcement Fund" within the Department of the Treasury for fees, cost recoveries and penalties associated with this program.

- Requires the Legislature to annually appropriate money from the enforcement fund for expenses related to the collection of information, administrative and enforcement.

- Allows the Division of Consumer Affairs to contract with an outside vendor to establish and maintain the program.

- Provides an effective date and authorizes the Director of Division of Consumer Affairs to take any administrative action necessary in advance for the implementation of the bill.

BILL DESCRIPTION

Assembly Committee Substitute for Assembly Bill No. 1624 of 2007 establishes a Prescription Monitoring Program in the Division of Consumer Affairs in the Department of Law and Public Safety. This program will monitoring controlled dangerous substance dispensed in New Jersey by a pharmacist.

This bill requires that pharmacy permit holders supply the division with certain information regarding prescribed controlled dangerous substances so that the division may identify the diversion of prescription drugs and request that the information be submitted to the division within 30 days after the prescription is dispensed.

The bill requires the division to review the prescription monitoring information provided by a pharmacy permit holder and, if there is reasonable cause to believe a violation of law or regulations or a breach of professional standards may have occurred, notify the appropriate law enforcement agency and professional licensing board, and provide prescription information required for an investigation.

The bill provides immunity to the division, pharmacy permit holder, pharmacist, or practitioner from civil liability arising from inaccuracy of any of the information submitted.

The bill establishes penalties for a pharmacy permit holder, or person designated by the holder, who knowingly fails to submit prescription monitoring information to the division or discloses data. They are subject to disciplinary action and a fine of up to $1,000. A person or entity other than a pharmacy permit holder who knowingly discloses data is subject to a fine of up to $10,000.

A fund to be known as the “Controlled Dangerous Substances Administration and Enforcement Fund” is established within the Department of the Treasury to collect fees, cost recoveries and penalties associated with this program. This fund will be used to pay for the establishment and maintenance of the program.

The bill provides an effective date of 18 months after enactment, but authorizes the Director of the division to take anticipatory administrative action in advance as necessary for its implementation.

FISCAL ANALYSIS

EXECUTIVE BRANCH

The Department of Law and Public Safety informally estimates the cost of implementing the provisions of this bill at $554,000 in the first year of enactment. This amount includes $278,000 in salaries and benefits for a program manager, program technician and two full-time

investigators; materials and supplies, at $3,000; and $273,000 for services other than personnel, specifically data processing.

After adjustment for inflation and deduction of certain fixed costs, the division estimates the cost of this bill at $567,000 and $578,000, in the second and third years, respectively.

The division further noted that any initial expenses will be funded by a FFY 2004 one-time Prescription Monitoring grant of $350,000. This federal grant was provided to the State to establish a prescription monitoring program and should cover the start up and discovery costs of running data.

OFFICE OF LEGISLATIVE SERVICES

The OLS concurs with the informal Executive estimate if the Division of Consumer Affairs implements the program. If Division of Consumer Affairs determines to contract with an outside vendor, however, for the implementation and/or maintenance, OLS estimates the cost of the program will increase.

In the first year $350,000 from a 2004 federal grant awarded under the Harold Rogers Prescription Monitoring Program will be provided to Division of Consumer Affairs. Additional federal funds may also become available through State application. Funding for future years is indeterminate and depends on the fees set by the Director of Division of Consumer Affairs to offset the monitoring service as well as fines and penalties collected from non-compliance.

Section:	*Law and Public Safety*
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This fiscal estimate has been prepared pursuant to P.L. 1980, c.67.