

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: No

VETO MESSAGE: No

GOVERNOR'S PRESS RELEASE ON SIGNING: No

FOLLOWING WERE PRINTED:

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REPORTS: No

HEARINGS: No

NEWSPAPER ARTICLES: No

RH/CL

Title 24.
Subtitle 1.
Chapter 6M.
(New)
Drug Donation
§§ 1-9 -
C.24:6M-1 to
24:6M-9
§10 - Note

P.L.2017, CHAPTER 254, *approved January 8, 2018*
Senate, No. 2560 (*First Reprint*)

1 AN ACT authorizing the establishment of drug donation programs,
2 and supplementing Title 24 ¹and Title 54¹ of the Revised
3 Statutes ¹and Title 54A of the New Jersey Statutes¹.
4

5 **BE IT ENACTED** by the Senate and General Assembly of the State
6 of New Jersey:
7

8 1. The Legislature finds and declares that the health of low-
9 income persons in the State can be improved, and the cost to the
10 State of providing health care to low-income persons can be
11 reduced, through the establishment of one or more programs that
12 provide for: the donation of unused over-the-counter drugs,
13 prescription drugs, and administration supplies, which would
14 otherwise be destroyed; and the redistribution of such unused drugs
15 and administration supplies to those persons who are most in need.
16

17 2. As used in ¹sections 1 through 7 of¹ this act:

18 “Administration supplies” means any supply associated with the
19 administration of prescription drugs, including, but not limited to,
20 diabetes test strips, nebulizers, syringes, and needles.

21 “Anti-rejection drug” means an over-the-counter drug or
22 prescription drug that suppresses the immune system to prevent or
23 reverse the rejection of a transplanted organ.

24 “Board” means the State Board of Pharmacy.

25 “Cancer drug” means a prescription drug that is used to treat
26 cancer or the side effects of cancer, or that is used to treat the side
27 effects of any other prescription drug that is used to treat cancer or
28 the side effects of cancer.

29 “Commissioner” means the Commissioner of Health.

30 ¹“Compounded drug” means a sterile or nonsterile compounded
31 formulation for dispensing or administration pursuant to a
32 prescription, that is prepared for a patient with needs that cannot be
33 met by a commercially available prescription drug.¹

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

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

¹Senate SBA committee amendments adopted June 15, 2017.

1 “Controlled dangerous substance” means the same as that term is
2 defined by N.J.S.2C:35-2.

3 ¹“Correctional facility” means a county or state correctional
4 facility, county juvenile detention facility, secure juvenile facility,
5 federal prison, or other comparable facility.¹

6 “Donated drug” means an over-the-counter drug or prescription
7 drug that has been donated to a redistributor in accordance with the
8 provisions of this act.

9 “Donor” means a drug manufacturer, wholesaler, repackager,
10 ¹“or reverse distributor” returns processor¹, ¹“or a” third-party
11 logistics provider,¹ health care facility, correctional facility,
12 pharmacy, or any other person or entity that is properly licensed and
13 authorized to possess prescription drugs, and which elects to donate
14 over-the-counter drugs, prescription drugs, or administration
15 supplies pursuant to this act.

16 “Drug donation program” means a program, established pursuant
17 to the provisions of this act, which accepts the donation of unused
18 over-the-counter drugs, prescription drugs, and administration
19 supplies that would otherwise be destroyed, and which provides for
20 the redistribution of those unused drugs and administration supplies
21 to persons who are most in need.

22 ¹“Grooming and hygiene product” is soap or cleaning solution,
23 shampoo, toothpaste, mouthwash, anti-perspirant, or sun tan lotion
24 or screen, regardless of whether the item meets the definition of
25 “over-the-counter drug.”¹

26 “Health care facility” means a physician’s office; a hospital; an
27 outpatient clinic; a federally qualified health center; a federally
28 qualified health center look-alike; a rural health clinic; ¹“a
29 disproportionate share hospital¹”; a clinic that provides services
30 under the federal Ryan White HIV/AIDS Program; a mental health
31 center or clinic; ¹a Veterans Affairs hospital;¹ and any other health
32 care facility licensed pursuant to P.L.1971, c.136 (C.26:2H-1 et
33 seq.), or a comparable facility licensed to operate within another
34 state.

35 “Indigent” means a person ¹“that” who¹ has an income that is
36 below 250 percent of the federal poverty level.

37 ¹“Out-of-State redistributor” means a health care facility,
38 pharmacy, wholesaler, returns processor, or other person or entity
39 that is properly licensed to operate in a state other than New Jersey,
40 and is authorized to dispense over-the-counter drugs and
41 prescription drugs, and which agrees to accept, repackage, transfer
42 to other redistributors, and, if otherwise authorized by law, dispense
43 donated drugs and administration supplies to eligible individuals
44 pursuant to a prescription drug donation program established under
45 the laws of the state in which the person or entity is located.

46 “Over-the-counter-drug” means a drug that contains a label that
47 meets the requirements of 21 CFR 201.66, including (1) a “Drug

1 Facts" panel; or (2) a statement of the "active ingredient" or
2 "active ingredients" with a list of those ingredients contained in the
3 compound, substance, or preparation. "Over-the-counter drug" does
4 not include a grooming and hygiene product.¹

5 "Prescriber" means a licensed physician, physician assistant, or
6 advanced practice nurse, or any other person who is authorized by
7 the appropriate State professional and occupational licensing board
8 to prescribe drugs and devices as provided by law.

9 "Prescription drug" means any drug, intended for use in humans,
10 which is required by federal or State law or regulation to be
11 dispensed only pursuant to a prescription. "Prescription drug"
12 includes cancer drugs and anti-rejection drugs, but does not include
13 any controlled dangerous substance ¹or compounded drug¹.

14 "Redistributor" means a health care facility, pharmacy,
15 ¹wholesaler, returns processor,¹ or any other person or entity that is
16 properly licensed and authorized to dispense over-the-counter drugs
17 and prescription drugs, and which agrees to accept, repackage,
18 transfer ¹to other redistributors¹, and ¹if otherwise authorized by
19 law,¹ dispense donated drugs and administration supplies to eligible
20 individuals ¹], or to other redistributors,]¹ pursuant to this act.
21 ¹"Redistributor" includes an out-of-state redistributor.¹

22 ¹["Out-of-State redistributor" means a health care facility,
23 pharmacy, or other person or entity that is properly licensed to
24 operate in a state other than New Jersey, and is authorized to
25 dispense over-the-counter drugs and prescription drugs, and which
26 agrees to accept, repackage, transfer, and dispense donated drugs
27 and administration supplies to eligible individuals, or to other
28 redistributors, pursuant to a prescription drug donation program
29 established under the laws of the state in which the person or entity
30 is located.]¹

31 ¹"Returns processor" shall mean the same as that term is defined
32 by 21 U.S.C. s.360eee(18). "Returns processor" includes a
33 reversedistributor.¹

34 "Tamper-evident packaging" means a package or container that
35 has an immediate, outer, or secondary seal that must be broken in
36 order to gain access to the container's contents. ¹"Tamper-evident
37 packaging" includes partially used single-unit dose or blister pack
38 and bottles or vials sealed in pouches or with tamper-evident tape.¹

39 "Third-party intermediary" means an organization that is not a
40 wholesaler or third-party logistics provider, and that facilitates the
41 donation or transfer of over-the-counter drugs, prescription drugs,
42 and administration supplies for a drug donation program established
43 pursuant to this act, but which does not take possession or
44 ownership of the drugs.

45 ¹"Transaction date" means the date at which ownership of the
46 drug was donated or transferred between two participants of the
47 program as established by contract or other arrangement. If no such

1 contract or arrangement exists, the transaction date shall be the date
2 the drug was accepted into inventory by the redistributor.¹

3
4 3. a. No later than six months after the enactment of this act,
5 the commissioner, in cooperation with the board, shall authorize
6 one or more private entities to establish and maintain a drug
7 donation program, pursuant to which a donor may donate over-the-
8 counter drugs, prescription drugs, and administration supplies to a
9 redistributor for final dispensing to an individual who meets the
10 eligibility criteria established by the entity for the purposes of its
11 program.

12 b. An entity that establishes a drug donation program pursuant
13 to this act may contract with a third-party intermediary to
14 implement and administer the program.

15 c. An entity that establishes a drug donation program pursuant
16 to this act shall develop, implement, and make available, upon
17 request of the commissioner, the board, or the public:

18 (1) standards and procedures for accepting, safely storing, and
19 dispensing donated drugs and administration supplies;

20 (2) standards and procedures for inspecting donated drugs to
21 ensure that the drugs are contained in sealed, tamper-evident
22 packaging, including, but not limited to, intact single-unit doses or
23 blister packs;

24 (3) standards and procedures for inspecting donated drugs to
25 ensure that the drugs are not adulterated or misbranded;

26 (4) eligibility criteria for individuals to receive donated drugs
27 and administration supplies dispensed under the program, which
28 criteria shall prioritize the dispensing of donated drugs and
29 administration supplies to individuals who are indigent, uninsured,
30 or enrolled in a public health benefits program, but may permit
31 dispensing to other individuals if a need for the donated drugs and
32 administration supplies is not identified among persons who are
33 indigent, uninsured, or enrolled in a public health benefits program;

34 (5) a means by which an individual may indicate ¹【their
35 eligibility】 that the individual is eligible¹ to receive donated drugs
36 and administration supplies under the program ¹, which may
37 comprise in part or whole of self-certification¹;

38 (6) a list of over-the-counter drugs and prescription drugs that
39 the program is seeking, will accept, and will not accept, including a
40 list of those drugs that an individual redistributor participating in
41 the program is seeking, will accept, and will not accept;

42 d. Donated over-the-counter drugs, prescription drugs, and
43 administration supplies may be transferred from one redistributor to
44 another redistributor in this State, and may be transferred to or from
45 a redistributor in another state, provided that such transfer is
46 permitted under the laws of that ¹other¹ state. The donation,
47 transfer, or facilitation of donations and transfers of over-the-
48 counter drugs or prescription drugs pursuant to this subsection shall

1 not be deemed to constitute wholesale distribution ¹and shall not
2 require licensing as a wholesaler¹.

3 e. (1) Any over-the-counter drugs ¹**[and]** ¹prescription drugs
4 ¹, and administration supplies¹ that a donor legally possesses,
5 including, but not limited to, over-the-counter drugs ¹**[and]** ¹
6 prescription drugs ¹, and administration supplies¹ that are
7 discontinued in a health care facility, and that would otherwise be
8 destroyed, are eligible for donation under this act.

9 (2) A prescription drug that can only be dispensed to a patient
10 who is registered with the manufacturer of that drug, in accordance
11 with requirements established by the federal Food and Drug
12 Administration, shall not be accepted or distributed by any drug
13 donation program.

14 f. A common carrier or contract carrier may be used to
15 transport donated over-the-counter drugs, prescription drugs, and
16 administration supplies, in accordance with manufacturer
17 recommendations, ¹including but not limited to,¹ from a donor to a
18 redistributor, from a redistributor to another redistributor, ¹from a
19 redistributor to a donor,¹ or from a redistributor to an eligible
20 patient.

21 g. The participation of any person, facility, or other entity in a
22 drug donation program established under this act shall be voluntary.
23

24 4. a. Donated drugs and administration supplies may be
25 accepted, transferred, and dispensed by a redistributor pursuant to
26 this act, provided that the following conditions are satisfied:

27 (1) the donated drugs ¹**[are not expired, and]**¹ are contained in a
28 sealed and tamper-evident package ¹**[**, including, but not limited to,
29 a single-unit dose or blister pack¹ that remains intact;

30 (2) the donated drugs and administration supplies are dispensed
31 to an eligible individual by a pharmacist or other health care
32 professional who is authorized by law to dispense over-the-counter
33 drugs and prescription drugs;

34 (3) the dispensing pharmacist or other health care professional
35 determines, prior to dispensing a donated drug, that the donated
36 drug is not adulterated or misbranded; ¹**[and]**¹

37 (4) the dispensing pharmacist or other health care professional
38 dispenses any donated prescription drugs or prescription
39 administration supplies to eligible individuals only pursuant to a
40 valid prescription ¹;

41 ¹(5) the dispensed drugs and administration supplies are in a new
42 container or have had all previous patient information on the
43 donated container redacted or removed;

44 ¹(6) the dispensed drugs and administration supplies are properly
45 labeled in accordance with the regulations of the board;

46 ¹(7) the dispensed drugs and administration supplies have an
47 expiration or beyond use date brought forward from the donated

1 drug that will not expire before the use by the patient based on the
2 prescribing practitioner's directions for use or, for over-the-counter
3 drugs, on the package's label; and

4 (8) an out-of-state redistributor complies with all laws and rules
5 in this State unless such laws or rules differ or conflict with the
6 laws or rules of the state in which the redistributor is located¹ .

7 b. A redistributor may accept over-the-counter drugs,
8 prescription drugs, and administration supplies from a donor located
9 in another state, provided that the transfer is permitted under the
10 laws of that other state.

11 c. ¹(1)¹ A redistributor may repackage donated over-the-
12 counter drugs, prescription drugs, or administration supplies before
13 transferring, storing, or dispensing the donated drugs or
14 administration supplies to an eligible individual, or before
15 transferring the donated drugs or administration supplies to another
16 redistributor.

17 ¹(2) Repackaged drugs shall be labeled with the drug name,
18 strength, and expiration date, and shall be kept in a separate
19 designated area until inspected and initialed by a pharmacist or
20 other health care professional.

21 (3) If multiple packaged donated drugs with varied expiration
22 dates are repackaged together, the shortest expiration date shall be
23 used.¹

24 d. Donated drugs and administration supplies shall be
25 segregated from other drug stocks, by either physical or electronic
26 means.

27 e. (1) A redistributor's receipt of reimbursement or payment
28 from another redistributor, a governmental agency, a pharmacy
29 benefit manager, a pharmacy services administration organization,
30 or a health care coverage program under this section¹, including a
31 usual and customary charge,¹ shall not be deemed to constitute the
32 resale of prescription drugs for the purposes of this act, or for the
33 purposes of any other law or regulation.

34 (2) A redistributor may ¹also¹ charge a handling fee to an
35 eligible individual who is dispensed a donated drug pursuant to this
36 act, provided that ¹, if the redistributor is for-profit,¹ the fee does
37 not exceed the reasonable costs of procuring, transporting,
38 inspecting, repackaging, storing, and dispensing the donated drug.
39 ¹~~【The】~~ ¹A¹ redistributor ¹that charges a handling fee pursuant to this
40 paragraph¹ shall maintain a record validating the charge, and shall
41 make that record available to the department ¹【,】¹ upon request.

42 f. (1) If a donor receives notice from a pharmacy or
43 pharmaceutical manufacturer regarding the recall of a donated over-
44 the-counter drug or prescription drug, or of donated administration
45 supplies, the donor shall provide notice of the recall to the
46 redistributor who received the recalled over-the-counter drug,
47 prescription drug, or administration supplies, unless the

1 redistributor has provided the donor with a written statement
2 attesting that the redistributor receives recall notices for all
3 transferred and dispensed drugs through other means.

4 (2) If a redistributor receives notice of a recall pursuant to
5 paragraph (1) of this subsection, the redistributor shall provide
6 notice of the recall to any other redistributor to whom it has
7 transferred the recalled over-the-counter drugs, prescription drugs,
8 or administration supplies, unless the ¹【secondary】 subsequent¹
9 redistributor has provided the ¹【primary】 previous¹ redistributor
10 with a written statement attesting that the ¹【secondary】 subsequent¹
11 redistributor receives recall notices for all transferred and dispensed
12 drugs through other means.

13 (3) Any redistributor who receives a notice of recall shall
14 perform a uniform destruction of all of the recalled over-the-counter
15 drugs, prescription drugs, or administration supplies in its
16 possession.

17 ¹g. Prior to the first donation from a new donor, a redistributor
18 shall verify and record the following as a donor record, and no other
19 donor information shall be required:

20 (1) the donor meets the definition of donor under this act;

21 (2) the donor's name, address, phone number, and license
22 number, if applicable;

23 (3) certification that the donor will not donate any controlled
24 dangerous substances; and

25 (4) certification that, if applicable, the donor will remove or
26 redact any patient names and prescription numbers on donated
27 drugs or otherwise maintain patient confidentiality by executing a
28 confidentiality agreement with the redistributor.

29 h. A drug manufacturer, repackager, pharmacy, or wholesaler
30 other than a returns processor participating in this program shall
31 comply with the requirements of 21 U.S.C. ss. 360eee-1 through
32 360eee-4 relating to drug supply chain security.

33 i. Donated drugs and administration supplies not accepted by the
34 redistributor shall be disposed by returning the drugs or supplies to
35 the donor, destroying the drugs or supplies by an incinerator or
36 other lawful method, or transferring it to a returns processor. A
37 record of disposed drugs and administration supplies shall consist
38 of the disposal method as described above, the date of disposal, and
39 the name, strength, and quantity of each drug disposed and the
40 name and quantity of any administration supplies disposed. No
41 other record of disposal shall be required.

42 j. All donated drugs and administration supplies received but not
43 yet accepted into inventory shall be kept in a separate designated
44 area. Prior to or upon accepting a donation or transfer into
45 inventory, a redistributor shall maintain a written or electronic
46 inventory of the donation, consisting of the transaction date, the
47 name, strength, and quantity of each accepted drug and the name
48 and quantity of any accepted administration supplies, and the name,

1 address, and phone number of the donor. This record shall not be
2 required if the two parties are under common ownership or common
3 control. No other record of donation shall be required.

4 k. An authorized recipient shall store and maintain donated
5 drugs physically or electronically separated from other inventory
6 and in a secure and temperature controlled environment that meets
7 the drug manufacturers' recommendations and United States
8 Pharmacopeial Convention (USP) standards.

9 l. All records required under this act shall be retained in physical
10 or electronic format, on or off the redistributor's premises for a
11 period of six years. A donor or redistributor may contract with one
12 another or a third-party entity to create or maintain records on each
13 other's behalf. An identifier, such as a serial number or barcode,
14 may be used in place of information required by a record or label
15 under this act if it allows for such information to be readily
16 retrievable. An identifier shall not be used on patient labels when
17 dispensing or administering a drug.

18 m. If a record of the transaction information or history of a
19 donation is required, the history shall begin with the acceptance of
20 the drugs, shall include all prior donations, and, if the drug was
21 previously dispensed, shall only include drug information required
22 to be on the patient label in accordance with board rules and
23 regulations.¹

24
25 ¹[5. A donor shall be allowed a credit against the tax that would
26 otherwise be due under the "New Jersey Gross Income Tax Act,"
27 P.L.1976, c.47 (C.54A:1-1 et seq.), for the taxable year in which a
28 donation was made pursuant to this act, in an amount equal to the
29 cost of any over-the-counter drugs, prescription drugs, and
30 administration supplies that were donated during the taxable year,
31 provided that:

32 a. the donor paid for, owned, or was responsible for, the over-
33 the-counter drugs, prescription drugs, or administration supplies;
34 and

35 b. the over-the-counter drugs, prescription drugs, or
36 administration supplies were donated to, and accepted by, a
37 redistributor in accordance with the provisions of this act.]¹

38
39 ¹[6.] 5.¹ a. Any donor, redistributor, third-party intermediary,
40 common carrier, contract carrier, governmental agency ¹, including
41 but not limited to the Department of Health and the board¹,
42 pharmacy benefit manager, pharmacy services administration
43 organization, health care coverage program, or other ¹[person or]¹
44 entity ¹[or person, including but not limited to volunteers,
45 employees, officers, directors, owners, partners, managers, and
46 members,¹ who acts reasonably and in good faith, within the scope
47 of a drug donation program, and in accordance with the provisions
48 of this act, shall be: (1) immune from civil or criminal liability for

1 any injury, death, or loss suffered by a person who is dispensed a
 2 donated drug¹ ~~[,]~~¹ or donated administration supplies under this act;
 3 and (2) exempt from any professional disciplinary action stemming
 4 from any act or omission associated with ¹any activity pursuant to
 5 this act, including but not limited to,¹ the donation, acceptance,
 6 ¹repackaging, transportation,¹ transfer, or dispensing of a donated
 7 drug or donated administration supplies ¹ ~~[pursuant to this act]~~¹.

8 b. A drug manufacturer ¹ ~~[or] ,~~¹ wholesaler ¹, or other entity
 9 participating in the supply chain of the donated drug or donated
 10 administration supplies¹ who acts reasonably and in good faith, in
 11 accordance with the provisions of this act, and as otherwise
 12 required by law, shall be immune from civil or criminal liability for
 13 any injury, death, or loss to a person or property stemming from any
 14 act or omission in association with ¹any activity pursuant to this act
 15 including but not limited to¹ the donation, acceptance,
 16 ¹repackaging,¹ transportation, ¹transfer,¹ or dispensing of an over-
 17 the-counter drug or prescription drug that is manufactured or
 18 distributed by the drug manufacturer ¹ ~~[or] ,~~¹ wholesaler ¹, or other
 19 entity¹ and donated pursuant to this act, including any liability
 20 resulting from a failure to transfer or communicate product or
 21 consumer information or the expiration date of the donated drug.

22 c. A redistributor who dispenses donated drugs or
 23 administration supplies that have been recalled shall be immune
 24 from civil or criminal liability for any injury, death or loss suffered
 25 by a person who is dispensed those drugs or administration
 26 supplies, provided that the redistributor was not notified of the
 27 recall by the donor, by another redistributor, or through other
 28 means, as provided in subsection ¹ ~~[g] f~~¹. of section 4 of this act.

29
 30 ¹ ~~[7.] 6.~~¹ The provisions of this act shall not be construed to
 31 restrict the use of drug samples by a health care professional who is
 32 licensed to prescribe drugs and devices during the course of the
 33 professional's duties at a health care facility or pharmacy.

34
 35 ¹ ~~[8.] 7.~~¹ Not later than six months after the date of enactment
 36 of this act, the commissioner, in consultation with the board ¹and
 37 the Director of the Division of Taxation in the Department of the
 38 Treasury¹, shall adopt rules and regulations, pursuant to the
 39 "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et
 40 seq.), as may be necessary to effectuate the purposes of this act.

41
 42 ¹8. a. For privilege periods beginning on or after the effective
 43 date of P.L. , c. (C.) (pending before the Legislature as this
 44 bill), a taxpayer that is a donor shall be allowed a credit against the
 45 tax imposed pursuant to section 5 of P.L.1945, c.162 (C.54:10A-5),
 46 in an amount equal to the sum of: the cost to the taxpayer of the
 47 over-the-counter drugs, prescription drugs, and administration

1 supplies as determined pursuant to 26 U.S.C. s.170(e)(3)(A); and
2 the verifiable cost to the taxpayer to make the donation of the over-
3 the-counter drugs, prescription drugs, and administration supplies to
4 a redistributor during the taxable year in accordance with a drug
5 donation program established pursuant to the provisions of P.L. ,
6 c. (C.) (pending before the Legislature as this bill), provided
7 that:

8 (1) the donor paid for, owned, or was responsible for the over-
9 the-counter drugs, prescription drugs, or administration supplies;

10 (2) the over-the-counter drugs, prescription drugs, or
11 administration supplies were donated to, and accepted by, a
12 redistributor in accordance with the provisions of P.L. ,
13 c. (C.) (pending before the Legislature as this bill); and

14 (3) the redistributor, which processed the donated drug, complies
15 with all recordkeeping requirements for nonsaleable returns to a
16 returns processor under federal law.

17 b. The order of priority of the application of the credit allowed
18 pursuant to this section and any other credits allowed by law shall
19 be as prescribed by the director. The amount of the credit applied
20 under this section against the corporation business tax liability of
21 the taxpayer for a privilege period, together with any other credits
22 allowed by law, shall not exceed 50 percent of the tax liability
23 otherwise due and shall not reduce the tax liability to an amount
24 less than the statutory minimum provided in subsection (e) of
25 section 5 of P.L.1945, c.162 (C.54:10A-5). The amount of the
26 credit allowable under this section which cannot be used to reduce
27 the taxpayer's corporation business tax liability for the privilege
28 period due to the limitations of this section may be carried forward
29 and applied to the earliest available use within the 20 privilege
30 periods immediately following the privilege period for which the
31 credit is allowed. The costs of the over-the-counter drugs,
32 prescription drugs, and administration supplies, and the costs to
33 make the donation to a redistributor, that are included in the
34 calculation of the credit allowed pursuant to this section shall not be
35 allowed as an amount calculated or claimed pursuant to any other
36 deduction or credit allowed under the corporation business tax.

37 c. As used in this section: "donor," "over-the-counter drugs,"
38 "prescription drugs," "administration supplies," "redistributor,"
39 "returns processor," and "drug donation program" shall mean the
40 same as those terms are defined by section 2 of P.L. , c. (C.)
41 (pending before the Legislature as this bill).¹

42
43 ^{19.} a. For taxable years beginning on or after the effective date
44 of P.L. , c. (C.) (pending before the Legislature as this bill),
45 a taxpayer that is a donor shall be allowed a credit against the tax
46 otherwise due under the "New Jersey Gross Income Tax Act,"
47 N.J.S.54A:1-1 et seq., in an amount equal to the sum of: the cost to
48 the taxpayer of the over-the-counter drugs, prescription drugs, and

1 administration supplies as determined pursuant to 26 U.S.C.
2 s.170(e)(3)(A); and the verifiable cost to the taxpayer to make the
3 donation of the over-the-counter drugs, prescription drugs, and
4 administration supplies to a redistributor during the taxable year in
5 accordance with a drug donation program established pursuant to
6 the provisions of P.L. _____, c. _____ (C. _____) (pending before the
7 Legislature as this bill), provided that:

8 (1) the donor paid for, owned, or was responsible for the over-
9 the-counter drugs, prescription drugs, or administration supplies;

10 (2) the over-the-counter drugs, prescription drugs, or
11 administration supplies were donated to, and accepted by, a
12 redistributor in accordance with the provisions of P.L. _____,
13 c. _____ (C. _____) (pending before the Legislature as this bill); and

14 (3) the redistributor, which processed the donated drug, complies
15 with all recordkeeping requirements for nonsaleable returns to a
16 returns processor under federal law.

17 b. (1) The order of priority of the application of the credit
18 allowed pursuant to this section and any other credits allowed by
19 law shall be as prescribed by the director. The amount of the credit
20 applied under this section against the gross income tax liability of
21 the taxpayer for a taxable year, together with any other credits
22 allowed by law, shall not exceed 50 percent of the tax liability
23 otherwise due. The amount of the credit allowable under this
24 section which cannot be used to reduce the taxpayer's gross income
25 tax liability for the taxable year due to the limitations of this section
26 may be carried forward and applied to the earliest available use
27 within the 20 taxable years immediately following the taxable year
28 for which the credit is allowed. The costs of the over-the-counter
29 drugs, prescription drugs, and administration supplies, and the costs
30 incurred in making the donation to a redistributor, that are included
31 in the calculation of the credit allowed pursuant to this section shall
32 not be allowed as an amount calculated or claimed pursuant to any
33 other deduction or credit allowed under the gross income tax.

34 (2) A business entity that is classified as a partnership for
35 federal income tax purposes shall not be allowed a credit directly
36 under the gross income tax, but the amount of credit of a taxpayer
37 in respect of a distributive share of partnership income shall be
38 determined by allocating to the taxpayer that proportion of the
39 credit acquired by the partnership that is equal to the taxpayer's
40 share, whether or not distributed, of the total distributive income or
41 gain of the partnership for its taxable year ending within or with the
42 taxpayer's taxable year. A New Jersey S corporation shall not be
43 allowed a credit directly under the gross income tax, but the amount
44 of credit of a taxpayer in respect of a pro rata share of S
45 Corporation income shall be determined by allocating to the
46 taxpayer that proportion of the credit acquired by the New Jersey S
47 Corporation that is equal to the taxpayer's share, whether or not
48 distributed, of the total pro rata share of S Corporation income of

1 the New Jersey S Corporation for its privilege period ending within
2 or with the taxpayer's taxable year.

3 c. As used in this section: "donor," "over-the-counter drugs,"
4 "prescription drugs," "administration supplies," "redistributor,"
5 "returns processor," and "drug donation program" shall mean the
6 same as those terms are defined by section 2 of P.L. , c. (C.)
7 (pending before the Legislature as this bill).¹
8

9 ¹~~[9.]~~ 10.¹ This act shall take effect on the 180th day next
10 following the date of enactment, except that the Commissioner of
11 Health ¹~~[and]~~ ¹, the Director of the State Board of Pharmacy ¹, and
12 the Director of the Division of Taxation in the Department of the
13 Treasury¹ may take such anticipatory administrative action in
14 advance thereof as shall be necessary for the implementation of this
15 act.

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Authorizes establishment of drug donation programs.

SENATE, No. 2560

STATE OF NEW JERSEY 217th LEGISLATURE

INTRODUCED SEPTEMBER 26, 2016

Sponsored by:

Senator SHIRLEY K. TURNER

District 15 (Hunterdon and Mercer)

Senator DAWN MARIE ADDIEGO

District 8 (Atlantic, Burlington and Camden)

SYNOPSIS

Authorizes establishment of drug donation programs.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 5/2/2017)

1 AN ACT authorizing the establishment of drug donation programs,
2 and supplementing Title 24 of the Revised Statutes.

3

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

6

7 1. The Legislature finds and declares that the health of low-
8 income persons in the State can be improved, and the cost to the
9 State of providing health care to low-income persons can be
10 reduced, through the establishment of one or more programs that
11 provide for: the donation of unused over-the-counter drugs,
12 prescription drugs, and administration supplies, which would
13 otherwise be destroyed; and the redistribution of such unused drugs
14 and administration supplies to those persons who are most in need.

15

16 2. As used in this act:

17 “Administration supplies” means any supply associated with the
18 administration of prescription drugs, including, but not limited to,
19 diabetes test strips, nebulizers, syringes, and needles.

20 “Anti-rejection drug” means an over-the-counter drug or
21 prescription drug that suppresses the immune system to prevent or
22 reverse the rejection of a transplanted organ.

23 “Board” means the State Board of Pharmacy.

24 “Cancer drug” means a prescription drug that is used to treat
25 cancer or the side effects of cancer, or that is used to treat the side
26 effects of any other prescription drug that is used to treat cancer or
27 the side effects of cancer.

28 “Commissioner” means the Commissioner of Health.

29 “Controlled dangerous substance” means the same as that term is
30 defined by N.J.S.2C:35-2.

31 “Donated drug” means an over-the-counter drug or prescription
32 drug that has been donated to a redistributor in accordance with the
33 provisions of this act.

34 “Donor” means a drug manufacturer, wholesaler, repackager, or
35 reverse distributor, or a health care facility, correctional facility,
36 pharmacy, or any other person or entity that is properly licensed and
37 authorized to possess prescription drugs, and which elects to donate
38 over-the-counter drugs, prescription drugs, or administration
39 supplies pursuant to this act.

40 “Drug donation program” means a program, established pursuant
41 to the provisions of this act, which accepts the donation of unused
42 over-the-counter drugs, prescription drugs, and administration
43 supplies that would otherwise be destroyed, and which provides for
44 the redistribution of those unused drugs and administration supplies
45 to persons who are most in need.

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

Matter underlined thus is new matter.

1 “Health care facility” means a physician’s office; a hospital; an
2 outpatient clinic; a federally qualified health center; a federally
3 qualified health center look-alike; a rural health clinic; a
4 disproportionate share hospital; a clinic that provides services under
5 the federal Ryan White HIV/AIDS Program; a mental health center
6 or clinic; and any other health care facility licensed pursuant to
7 P.L.1971, c.136 (C.26:2H-1 et seq.), or a comparable facility
8 licensed to operate within another state.

9 “Indigent” means a person that has an income that is below 250
10 percent of the federal poverty level.

11 “Prescriber” means a licensed physician, physician assistant, or
12 advanced practice nurse, or any other person who is authorized by
13 the appropriate State professional and occupational licensing board
14 to prescribe drugs and devices as provided by law.

15 “Prescription drug” means any drug, intended for use in humans,
16 which is required by federal or State law or regulation to be
17 dispensed only pursuant to a prescription. “Prescription drug”
18 includes cancer drugs and anti-rejection drugs, but does not include
19 any controlled dangerous substance.

20 “Redistributor” means a health care facility, pharmacy, or any
21 other person or entity that is properly licensed and authorized to
22 dispense over-the-counter drugs and prescription drugs, and which
23 agrees to accept, repackage, transfer, and dispense donated drugs
24 and administration supplies to eligible individuals, or to other
25 redistributors, pursuant to this act.

26 “Out-of-State redistributor” means a health care facility,
27 pharmacy, or other person or entity that is properly licensed to
28 operate in a state other than New Jersey, and is authorized to
29 dispense over-the-counter drugs and prescription drugs, and which
30 agrees to accept, repackage, transfer, and dispense donated drugs
31 and administration supplies to eligible individuals, or to other
32 redistributors, pursuant to a prescription drug donation program
33 established under the laws of the state in which the person or entity
34 is located.

35 “Tamper-evident packaging” means a package or container that
36 has an immediate, outer, or secondary seal that must be broken in
37 order to gain access to the container’s contents.

38 “Third-party intermediary” means an organization that is not a
39 wholesaler or third-party logistics provider, and that facilitates the
40 donation or transfer of over-the-counter drugs, prescription drugs,
41 and administration supplies for a drug donation program established
42 pursuant to this act, but which does not take possession or
43 ownership of the drugs.

44

45 3. a. No later than six months after the enactment of this act,
46 the commissioner, in cooperation with the board, shall authorize
47 one or more private entities to establish and maintain a drug
48 donation program, pursuant to which a donor may donate over-the-

1 counter drugs, prescription drugs, and administration supplies to a
2 redistributor for final dispensing to an individual who meets the
3 eligibility criteria established by the entity for the purposes of its
4 program.

5 b. An entity that establishes a drug donation program pursuant
6 to this act may contract with a third-party intermediary to
7 implement and administer the program.

8 c. An entity that establishes a drug donation program pursuant
9 to this act shall develop, implement, and make available, upon
10 request of the commissioner, the board, or the public:

11 (1) standards and procedures for accepting, safely storing, and
12 dispensing donated drugs and administration supplies;

13 (2) standards and procedures for inspecting donated drugs to
14 ensure that the drugs are contained in sealed, tamper-evident
15 packaging, including, but not limited to, intact single-unit doses or
16 blister packs;

17 (3) standards and procedures for inspecting donated drugs to
18 ensure that the drugs are not adulterated or misbranded;

19 (4) eligibility criteria for individuals to receive donated drugs
20 and administration supplies dispensed under the program, which
21 criteria shall prioritize the dispensing of donated drugs and
22 administration supplies to individuals who are indigent, uninsured,
23 or enrolled in a public health benefits program, but may permit
24 dispensing to other individuals if a need for the donated drugs and
25 administration supplies is not identified among persons who are
26 indigent, uninsured, or enrolled in a public health benefits program;

27 (5) a means by which an individual may indicate their eligibility
28 to receive donated drugs and administration supplies under the
29 program;

30 (6) a list of over-the-counter drugs and prescription drugs that
31 the program is seeking, will accept, and will not accept, including a
32 list of those drugs that an individual redistributor participating in
33 the program is seeking, will accept, and will not accept;

34 d. Donated over-the-counter drugs, prescription drugs, and
35 administration supplies may be transferred from one redistributor to
36 another redistributor in this State, and may be transferred to or from
37 a redistributor in another state, provided that such transfer is
38 permitted under the laws of that state. The donation, transfer, or
39 facilitation of donations and transfers of over-the-counter drugs or
40 prescription drugs pursuant to this subsection shall not be deemed
41 to constitute wholesale distribution.

42 e. (1) Any over-the-counter drugs and prescription drugs that a
43 donor legally possesses, including, but not limited to, over-the-
44 counter drugs and prescription drugs that are discontinued in a
45 health care facility, and that would otherwise be destroyed, are
46 eligible for donation under this act.

47 (2) A prescription drug that can only be dispensed to a patient
48 who is registered with the manufacturer of that drug, in accordance

1 with requirements established by the federal Food and Drug
2 Administration, shall not be accepted or distributed by any drug
3 donation program.

4 f. A common carrier or contract carrier may be used to
5 transport donated over-the-counter drugs, prescription drugs, and
6 administration supplies, in accordance with manufacturer
7 recommendations, from a donor to a redistributor, from a
8 redistributor to another redistributor, or from a redistributor to an
9 eligible patient.

10 g. The participation of any person, facility, or other entity in a
11 drug donation program established under this act shall be voluntary.

12

13 4. a. Donated drugs and administration supplies may be
14 accepted, transferred, and dispensed by a redistributor pursuant to
15 this act, provided that the following conditions are satisfied:

16 (1) the donated drugs are not expired, and are contained in a
17 sealed and tamper-evident package, including, but not limited to, a
18 single-unit dose or blister pack that remains intact;

19 (2) the donated drugs and administration supplies are dispensed
20 to an eligible individual by a pharmacist or other health care
21 professional who is authorized by law to dispense over-the-counter
22 drugs and prescription drugs;

23 (3) the dispensing pharmacist or other health care professional
24 determines, prior to dispensing a donated drug, that the donated
25 drug is not adulterated or misbranded; and

26 (4) the dispensing pharmacist or other health care professional
27 dispenses any donated prescription drugs or prescription
28 administration supplies to eligible individuals only pursuant to a
29 valid prescription.

30 b. A redistributor may accept over-the-counter drugs,
31 prescription drugs, and administration supplies from a donor located
32 in another state, provided that the transfer is permitted under the
33 laws of that other state.

34 c. A redistributor may repackage donated over-the-counter
35 drugs, prescription drugs, or administration supplies before
36 transferring, storing, or dispensing the donated drugs or
37 administration supplies to an eligible individual, or before
38 transferring the donated drugs or administration supplies to another
39 redistributor.

40 d. Donated drugs and administration supplies shall be
41 segregated from other drug stocks, by either physical or electronic
42 means.

43 e. (1) A redistributor's receipt of reimbursement or payment
44 from another redistributor, a governmental agency, a pharmacy
45 benefit manager, a pharmacy services administration organization,
46 or a health care coverage program under this section shall not be
47 deemed to constitute the resale of prescription drugs for the

1 purposes of this act, or for the purposes of any other law or
2 regulation.

3 (2) A redistributor may charge a handling fee to an eligible
4 individual who is dispensed a donated drug pursuant to this act,
5 provided that the fee does not exceed the reasonable costs of
6 procuring, transporting, inspecting, repackaging, storing, and
7 dispensing the donated drug. The redistributor shall maintain a
8 record validating the charge, and shall make that record available to
9 the department, upon request.

10 f. (1) If a donor receives notice from a pharmacy or
11 pharmaceutical manufacturer regarding the recall of a donated over-
12 the-counter drug or prescription drug, or of donated administration
13 supplies, the donor shall provide notice of the recall to the
14 redistributor who received the recalled over-the-counter drug,
15 prescription drug, or administration supplies, unless the
16 redistributor has provided the donor with a written statement
17 attesting that the redistributor receives recall notices for all
18 transferred and dispensed drugs through other means.

19 (2) If a redistributor receives notice of a recall pursuant to
20 paragraph (1) of this subsection, the redistributor shall provide
21 notice of the recall to any other redistributor to whom it has
22 transferred the recalled over-the-counter drugs, prescription drugs,
23 or administration supplies, unless the secondary redistributor has
24 provided the primary redistributor with a written statement attesting
25 that the secondary redistributor receives recall notices for all
26 transferred and dispensed drugs through other means.

27 (3) Any redistributor who receives a notice of recall shall
28 perform a uniform destruction of all of the recalled over-the-counter
29 drugs, prescription drugs, or administration supplies in its
30 possession.

31

32 5. A donor shall be allowed a credit against the tax that would
33 otherwise be due under the "New Jersey Gross Income Tax Act,"
34 P.L.1976, c.47 (C.54A:1-1 et seq.), for the taxable year in which a
35 donation was made pursuant to this act, in an amount equal to the
36 cost of any over-the-counter drugs, prescription drugs, and
37 administration supplies that were donated during the taxable year,
38 provided that:

39 a. the donor paid for, owned, or was responsible for, the over-
40 the-counter drugs, prescription drugs, or administration supplies;
41 and

42 b. the over-the-counter drugs, prescription drugs, or
43 administration supplies were donated to, and accepted by, a
44 redistributor in accordance with the provisions of this act.

45

46 6. a. Any donor, redistributor, third-party intermediary,
47 common carrier, contract carrier, governmental agency, pharmacy
48 benefit manager, pharmacy services administration organization,

1 health care coverage program, or other person or entity who acts
2 reasonably and in good faith, within the scope of a drug donation
3 program, and in accordance with the provisions of this act, shall be:
4 (1) immune from civil or criminal liability for any injury, death, or
5 loss suffered by a person who is dispensed a donated drug, or
6 donated administration supplies under this act; and (2) exempt from
7 any professional disciplinary action stemming from any act or
8 omission associated with the donation, acceptance, transfer, or
9 dispensing of a donated drug or donated administration supplies
10 pursuant to this act.

11 b. A drug manufacturer or wholesaler who acts reasonably and
12 in good faith, in accordance with the provisions of this act, and as
13 otherwise required by law, shall be immune from civil or criminal
14 liability for any injury, death, or loss to a person or property
15 stemming from any act or omission in association with the
16 donation, acceptance, transportation, or dispensing of an over-the-
17 counter drug or prescription drug that is manufactured or distributed
18 by the drug manufacturer or wholesaler and donated pursuant to this
19 act, including any liability resulting from a failure to transfer or
20 communicate product or consumer information or the expiration
21 date of the donated drug.

22 c. A redistributor who dispenses donated drugs or
23 administration supplies that have been recalled shall be immune
24 from civil or criminal liability for any injury, death or loss suffered
25 by a person who is dispensed those drugs or administration
26 supplies, provided that the redistributor was not notified of the
27 recall by the donor, by another redistributor, or through other
28 means, as provided in subsection g. of section 4 of this act.
29

30 7. The provisions of this act shall not be construed to restrict
31 the use of drug samples by a health care professional who is
32 licensed to prescribe drugs and devices during the course of the
33 professional's duties at a health care facility or pharmacy.
34

35 8. Not later than six months after the date of enactment of this
36 act, the commissioner, in consultation with the board, shall adopt
37 rules and regulations, pursuant to the "Administrative Procedure
38 Act," P.L.1968, c.410 (C.52:14B-1 et seq.), as may be necessary to
39 effectuate the purposes of this act.
40

41 9. This act shall take effect on the 180th day next following the
42 date of enactment, except that the Commissioner of Health and the
43 Director of the State Board of Pharmacy may take such anticipatory
44 administrative action in advance thereof as shall be necessary for
45 the implementation of this act.

STATEMENT

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This bill would allow private entities to voluntarily establish drug donation programs, pursuant to which health care facilities, pharmacies, pharmaceutical manufacturers, and similar entities will be permitted to donate over-the-counter drugs, prescription drugs, and administration supplies for use by people who are indigent, uninsured, or underinsured. An entity electing to establish a drug donation program may contract with a third-party intermediary to implement and administer the program.

The bill would provide, in particular, that drug manufacturers, wholesalers, repackagers, and reverse distributors, as well as health care facilities and pharmacies, will be permitted to donate unexpired over-the-counter and prescription medications that are contained in tamper-evident packaging, or sealed in intact single-dose units or blister packaging. The bill would permit the donation of such over-the-counter and prescription medications as cancer drugs, anti-rejection drugs, and drugs that have been discontinued in a health care facility, but it would not permit the donation of controlled dangerous substances, or prescription drugs that can only be dispensed to a patient who is registered with the drug manufacturer. The bill would provide that donations may be accepted from donors located in another state, provided that the donation is permitted under the laws of that other state. It would further provide that drug donors will be allowed a credit against their State gross income taxes in an amount that is equal to the cost of the drugs that were donated during the taxable year.

Under the bill's provisions, drugs and supplies are to be donated to redistributors, including health care facilities and pharmacies. Redistributors will be required to inspect the donated drugs to determine whether they have been adulterated or misbranded, and would be required to separate any donated drugs from other drug stocks. Redistributors would be permitted to repackage donated drugs, or transfer donated drugs and administration supplies to another redistributor. Donated drugs and administration supplies may be transferred to, and accepted from, redistributors located in another state, provided that the transfer is permitted under a drug donation program established in that other state.

Redistributors will be required to establish eligibility criteria for individuals to receive donated over-the-counter drugs and prescription drugs, with priority being granted to persons who are indigent, uninsured, or underinsured. Donated drugs may not be resold by any person or entity, including a redistributor; however, redistributors are authorized by the bill to charge a reasonable handling fee to individuals who are dispensed a donated drug. The handling fee may not exceed the actual validated cost of transporting, inspecting, repackaging, storing, and dispensing the over-the-counter drug or prescription drug.

1 The bill would specify that donated prescription drugs may only
2 be dispensed, pursuant to a valid prescription, by a pharmacist or
3 other health care professional who is authorized by law to dispense
4 prescription medications.

5 The bill provides that, whenever a donor receives a recall notice
6 for a donated drug, the donor is to provide notice of the recall to
7 any redistributor to whom it donated the recalled drug, unless the
8 redistributor has provided the donor with a written statement
9 attesting that the redistributor receives such recall notices through
10 other means. In the same respect, if a redistributor has transferred a
11 donated drug to another redistributor, and the drug is later recalled,
12 the primary redistributor will be required to notify secondary
13 redistributors of the recall, unless the secondary redistributors have
14 provided a written statement attesting that they receive recall
15 notices through other means. Upon receiving notice of a recall,
16 whether from a donor, a redistributor, or through other means, a
17 redistributor will be required to perform a uniform destruction of all
18 the recalled drugs in their possession.

19 Any person or entity establishing a drug donation program under
20 the bill's provisions will be required to: (1) develop, implement,
21 and make available to the Commissioner of Health, the Board of
22 Pharmacy, and members of the public, upon request, standards and
23 procedures for meeting the requirements of the bill; and (2)
24 develop, and make available, a list of over-the-counter drugs and
25 prescription drugs that the program is seeking, accepting, or not
26 accepting including, including a list of over-the-counter drugs and
27 prescription drugs that an individual redistributor participating in
28 the program is seeking or will not accept.

29 Any person or entity that acts reasonably, and in good faith, in
30 accordance with the provisions of the bill, and within the scope of a
31 drug donation program established thereunder, will be immune from
32 civil and criminal liability for any injury to, or the death of, an
33 individual to whom a donated drug is dispensed, and will similarly
34 be exempt from disciplinary action related to any act or omission
35 associated with a donated drug. Drug manufacturers and
36 wholesalers will also be immune from civil or criminal liability for
37 any injury, death, or loss related to donated drugs that they
38 manufacture or distribute. Redistributors will be immune from civil
39 or criminal liability for dispensing a donated drug that has been
40 recalled, but only if the redistributor was not notified of the recall.

41 Nothing in the bill's provisions would be construed to restrict the
42 use of drug samples by a licensed prescriber during the course of
43 the prescriber's duties at a health care facility or pharmacy.

SENATE HEALTH, HUMAN SERVICES AND SENIOR
CITIZENS COMMITTEE

STATEMENT TO

SENATE, No. 2560

STATE OF NEW JERSEY

DATED: MAY 1, 2017

The Senate Health, Human Services and Senior Citizens Committee reports favorably Senate Bill No. 2560.

This bill would allow private entities to voluntarily establish drug donation programs, pursuant to which health care facilities, pharmacies, pharmaceutical manufacturers, and similar entities will be permitted to donate over-the-counter drugs, prescription drugs, and administration supplies for use by people who are indigent, uninsured, or underinsured. An entity electing to establish a drug donation program may contract with a third-party intermediary to implement and administer the program.

The bill would provide, in particular, that drug manufacturers, wholesalers, repackagers, and reverse distributors, as well as health care facilities and pharmacies, will be permitted to donate unexpired over-the-counter and prescription medications that are contained in tamper-evident packaging, or sealed in intact single-dose units or blister packaging. The bill would permit the donation of such over-the-counter and prescription medications as cancer drugs, anti-rejection drugs, and drugs that have been discontinued in a health care facility, but it would not permit the donation of controlled dangerous substances, or prescription drugs that can only be dispensed to a patient who is registered with the drug manufacturer. The bill would provide that donations may be accepted from donors located in another state, provided that the donation is permitted under the laws of that other state. It would further provide that drug donors will be allowed a credit against their State gross income taxes in an amount that is equal to the cost of the drugs that were donated during the taxable year.

Under the bill's provisions, drugs and supplies are to be donated to redistributors, including health care facilities and pharmacies. Redistributors will be required to inspect the donated drugs to determine whether they have been adulterated or misbranded, and would be required to separate any donated drugs from other drug stocks. Redistributors would be permitted to repackage donated drugs, or transfer donated drugs and administration supplies to another redistributor. Donated drugs and administration supplies may be transferred to, and accepted from, redistributors located in another

state, provided that the transfer is permitted under a drug donation program established in that other state.

Redistributors will be required to establish eligibility criteria for individuals to receive donated over-the-counter drugs and prescription drugs, with priority being granted to persons who are indigent, uninsured, or underinsured. Donated drugs may not be resold by any person or entity, including a redistributor; however, redistributors are authorized by the bill to charge a reasonable handling fee to individuals who are dispensed a donated drug. The handling fee may not exceed the actual validated cost of transporting, inspecting, repackaging, storing, and dispensing the over-the-counter drug or prescription drug.

The bill would specify that donated prescription drugs may only be dispensed, pursuant to a valid prescription, by a pharmacist or other health care professional who is authorized by law to dispense prescription medications.

The bill provides that, whenever a donor receives a recall notice for a donated drug, the donor is to provide notice of the recall to any redistributor to whom it donated the recalled drug, unless the redistributor has provided the donor with a written statement attesting that the redistributor receives such recall notices through other means. In the same respect, if a redistributor has transferred a donated drug to another redistributor, and the drug is later recalled, the primary redistributor will be required to notify secondary redistributors of the recall, unless the secondary redistributors have provided a written statement attesting that they receive recall notices through other means. Upon receiving notice of a recall, whether from a donor, a redistributor, or through other means, a redistributor will be required to perform a uniform destruction of all the recalled drugs in their possession.

Any person or entity establishing a drug donation program under the bill's provisions will be required to: (1) develop, implement, and make available to the Commissioner of Health, the Board of Pharmacy, and members of the public, upon request, standards and procedures for meeting the requirements of the bill; and (2) develop, and make available, a list of over-the-counter drugs and prescription drugs that the program is seeking, accepting, or not accepting including, including a list of over-the-counter drugs and prescription drugs that an individual redistributor participating in the program is seeking or will not accept.

Any person or entity that acts reasonably, and in good faith, in accordance with the provisions of the bill, and within the scope of a drug donation program established thereunder, will be immune from civil and criminal liability for any injury to, or the death of, an individual to whom a donated drug is dispensed, and will similarly be exempt from disciplinary action related to any act or omission associated with a donated drug. Drug manufacturers and wholesalers

will also be immune from civil or criminal liability for any injury, death, or loss related to donated drugs that they manufacture or distribute. Redistributors will be immune from civil or criminal liability for dispensing a donated drug that has been recalled, but only if the redistributor was not notified of the recall.

Nothing in the bill's provisions would be construed to restrict the use of drug samples by a licensed prescriber during the course of the prescriber's duties at a health care facility or pharmacy.

SENATE BUDGET AND APPROPRIATIONS COMMITTEE

STATEMENT TO

SENATE, No. 2560

with committee amendments

STATE OF NEW JERSEY

DATED: JUNE 15, 2017

The Senate Budget and Appropriations Committee reports favorably Senate Bill No. 2560, with committee amendments.

As amended, this bill allows private entities to voluntarily establish drug donation programs, pursuant to which health care facilities, pharmacies, pharmaceutical manufacturers, and similar entities will be permitted to donate over-the-counter drugs, prescription drugs, and administration supplies for use by people who are indigent, uninsured, or underinsured. An entity electing to establish a drug donation program may contract with a third-party intermediary to implement and administer the program.

The bill provides, in particular, that drug manufacturers, wholesalers, repackagers, returns processors, and third-party logistics providers, as well as health care facilities and pharmacies, will be permitted to donate unexpired over-the-counter and prescription medications that are contained in a sealed and tamper-evident packaging that remains intact. The bill permits the donation of such over-the-counter and prescription medications as cancer drugs, anti-rejection drugs, and drugs that have been discontinued in a health care facility, but does not permit the donation of controlled dangerous substances, compounded drugs, or prescription drugs that can only be dispensed to a patient who is registered with the drug manufacturer. The bill provides that donations may be accepted from donors located in another state, provided that the donation is permitted under the laws of that other state. The bill further provides that drug donors are allowed a corporation business tax or gross income tax credit equal to the sum of: the cost of the over-the-counter drugs, prescription drugs, and administration supplies; and the verifiable cost incurred to make the donation of the drugs and supplies.

Under the bill, drugs and supplies are to be donated to redistributors, including health care facilities, pharmacies, wholesalers, and return processors. Redistributors will be required to inspect the donated drugs to determine whether they have been adulterated or misbranded, and will be required to separate any donated drugs from other drug stocks. Redistributors are permitted to repackage donated drugs and administration supplies, or transfer donated drugs and administration supplies to another redistributor. Donated drugs and

administration supplies may be transferred to, and accepted from, redistributors located in another state, provided that the transfer is permitted under a drug donation program established in that other state.

Redistributors will be required to establish eligibility criteria for individuals to receive donated over-the-counter drugs and prescription drugs, with priority being granted to persons who are indigent, uninsured, or underinsured. Donated drugs are nonsalable and may not be resold by any person or entity, including a redistributor; however, redistributors are authorized by the bill to charge a reasonable handling fee to individuals who are dispensed a donated drug. The handling fee may not exceed the actual validated cost of transporting, inspecting, repackaging, storing, and dispensing the over-the-counter drug or prescription drug, if the redistributor is for-profit.

The bill specifies that donated prescription drugs may only be dispensed, pursuant to a valid prescription, by a pharmacist or other health care professional who is authorized by law to dispense prescription medications.

The bill provides that, whenever a donor receives a recall notice for a donated drug, the donor is to provide notice of the recall to any redistributor to whom it donated the recalled drug, unless the redistributor has provided the donor with a written statement attesting that the redistributor receives such recall notices through other means. In the same respect, if a redistributor has transferred a donated drug to another redistributor, and the drug is later recalled, the primary redistributor will be required to notify secondary redistributors of the recall, unless the subsequent redistributors have provided a written statement attesting that they receive recall notices through other means. Upon receiving notice of a recall, whether from a donor, a redistributor, or through other means, a redistributor will be required to perform a uniform destruction of all the recalled drugs in their possession.

The bill requires that, prior to the first donation from a new donor, a redistributor must verify and record the following as a donor record:

- (1) The donor meets the definition of donor under this bill;
- (2) The donor's name, address, phone number, and license number, if applicable;
- (3) Certification that the donor will not donate any controlled dangerous substances; and
- (4) Certification that, if applicable, the donor will remove or redact any patient names and prescription numbers on donated drugs or otherwise maintain patient confidentiality by executing a confidentiality agreement with the redistributor.

Any person or entity establishing a drug donation program under the bill will be required to: (1) develop, implement, and make available to the Commissioner of Health, the Board of Pharmacy, and members of the public, upon request, standards and procedures for

meeting the requirements of the bill; and (2) develop, and make available, a list of over-the-counter drugs and prescription drugs that the program is seeking, accepting, or not accepting, including a list of over-the-counter drugs and prescription drugs that an individual redistributor participating in the program is seeking or will not accept.

Any person or entity that acts reasonably, and in good faith, in accordance with the bill, and within the scope of a drug donation program established thereunder, will be immune from civil and criminal liability for any injury to, or the death of, an individual to whom a donated drug is dispensed, and will similarly be exempt from disciplinary action related to any act or omission associated with an activity pursuant to the bill. Drug manufacturers, wholesalers, or other entities participating in the supply chain of the donated drug or donated administration supplies will also be immune from civil or criminal liability for any injury, death, or loss related to any activity pursuant to the bill. Redistributors will be immune from civil or criminal liability for dispensing a donated drug that has been recalled, but only if the redistributor was not notified of the recall.

Nothing in the bill's provisions would be construed to restrict the use of drug samples by a licensed prescriber during the course of the prescriber's duties at a health care facility or pharmacy.

COMMITTEE AMENDMENTS:

The amendments add requirements to the current conditions under which donated drugs and administration supplies may be dispensed by a redistributor, specify how repackaged drugs are to be labeled, and clarify certain limitations on handling charges of for-profit redistributors.

The amendments add language to require redistributors to verify and record certain information from each new donor participating in a program.

The amendments specify the procedures for the disposal of donated drugs and administration supplies not accepted as a donation, and incorporate certain additional record keeping, inventory, and storage procedures for donated drugs and administration supplies.

The amendments clarify that the gross income tax credit is equal to the sum of: the cost of the donated over-the-counter drugs, prescription drugs, and administration supplies; and the verifiable cost to make the donation of the drugs and supplies.

The amendments establish a parallel tax credit for donors under the corporation business tax.

The amendments clarify the civil and criminal liability granted by the bill for certain persons participating in a drug donation program.

The amendments revise certain defined terms provided by the bill and incorporate definitions for certain other terms and phrases used for purposes of the bill.

The amendments make certain other technical corrections as to punctuation, grammar, and internal cross-references.

FISCAL IMPACT:

The oversight of private drug donation programs by the Department of Health (DOH) would entail indeterminate annual costs to the State. The scope and scale of oversight activities would be subject to the substantial discretion of the DOH. Without any indication from the department on how it would implement the bill, the OLS cannot estimate the cost.

The bill's provisions that allow donors to receive credits against their Gross Income Tax (GIT) or Corporation Business Tax (CBT) liabilities would lead to an indeterminate annual reduction in State revenues. The amount of forgone revenue would depend on the number of entities that are subject to the GIT or CBT and participate as donors, and the value of the drugs that they donate. Many of the entities that are likely to participate as donors are tax-exempt nonprofit organizations and so would not be affected by the tax credit provisions.

The bill could possibly lead to a reduction in annual costs for State programs that pay for prescription drugs, such as Medicaid and the Pharmaceutical Assistance for the Aged and Disabled (PAAD) program. The bill allows each authorized drug donation program to establish its own eligibility criteria for individuals to receive donated drugs, but specifies that they must prioritize individuals who have low incomes, are uninsured or enrolled in a public health benefits program. To the extent that donated drugs are provided to public program participants, costs in those programs may be reduced.

LEGISLATIVE FISCAL ESTIMATE

[First Reprint]

SENATE, No. 2560 STATE OF NEW JERSEY 217th LEGISLATURE

DATED: JUNE 22, 2017

SUMMARY

- Synopsis:** Authorizes establishment of drug donation programs.
- Type of Impact:** Indeterminate net impact on annual General Fund expenditures, and an annual revenue decrease to the Property Tax Relief Fund and the General Fund.
- Agencies Affected:** Department of Health; State Board of Pharmacy; Department of the Treasury; possibly Department of Human Services.

Office of Legislative Services Estimate

| Fiscal Impact | <u>Annual</u> |
|----------------------|--|
| State Cost | Indeterminate net impact – See comments below. |
| State Revenue | Indeterminate decrease – See comments below. |

- The Office of Legislative Services (OLS) finds that the bill would affect State finances in multiple ways, resulting in an indeterminate annual net impact to the State.
- The oversight of private drug donation programs by the Department of Health (DOH) would entail indeterminate annual costs to the State. The scope and scale of oversight activities would be subject to the substantial discretion of the DOH. Without any indication from the department on how it would implement the bill, the OLS cannot estimate the cost.
- The bill's provisions that allow donors to receive credits against their Gross Income Tax (GIT) or Corporation Business Tax (CBT) liabilities would lead to an indeterminate annual reduction in State revenues. The amount of forgone revenue would depend on the number of entities that are subject to the GIT or CBT and participate as donors, and the value of the drugs that they donate. Many of the entities that are likely to participate as donors are tax-exempt nonprofit organizations and so would not be affected by the tax credit provisions.
- The bill could possibly lead to a reduction in annual costs for State programs that pay for prescription drugs, such as Medicaid and the Pharmaceutical Assistance for the Aged and

Disabled (PAAD) program. The bill allows each authorized drug donation program to establish its own eligibility criteria for individuals to receive donated drugs, but specifies that they must prioritize individuals who have low incomes, are uninsured or enrolled in a public health benefits program. To the extent that donated drugs are provided to public program participants, costs in those programs may be reduced.

BILL DESCRIPTION

Senate Bill No. 2560 (1R) of 2016 allows private entities to voluntarily establish drug donation programs, pursuant to which health care facilities, pharmacies, pharmaceutical manufacturers, and similar entities will be permitted to donate over-the-counter drugs, prescription drugs, and administration supplies for use by people who are indigent, uninsured, or underinsured.

The bill requires the DOH, in consultation with the State Board of Pharmacy, to authorize private entities to operate drug donation programs and to adopt implementing rules and regulations.

The bill also allows drug donors a credit against their GIT or CBT liabilities in an amount equal to the cost of any over-the-counter drugs, prescription drugs, and administration supplies donated to private drug donation programs; and the verifiable cost of making the donation. The amount of the credit, together with any other credits allowed by law, may not exceed 50 percent of the tax liability otherwise due, but any unused amount may be carried forward and applied against tax liabilities in future tax years.

FISCAL ANALYSIS

EXECUTIVE BRANCH

None received.

OFFICE OF LEGISLATIVE SERVICES

The OLS finds that the bill would affect State finances in multiple ways, resulting in an indeterminate annual net impact to the State.

The bill may result in an indeterminate annual State expenditure increase for the oversight of private drug donation programs, which would be conducted primarily by the DOH. The bill requires the department, in consultation with the State Board of Pharmacy, to authorize private entities to operate drug donation programs and to adopt implementing rules and regulations. The bill grants substantial discretion to the DOH concerning its program oversight activities. Without any indication from the department on how it would implement the bill, the OLS cannot estimate the associated expenditures. It may be reasonable to expect the DOH to establish an oversight operation with annual costs in the hundreds of thousands of dollars.

The bill's provisions that allow donors to receive credits against their GIT or CBT liabilities would lead to an indeterminate annual reduction in State revenues, which are deposited in the Property Tax Relief Fund and the General Fund, respectively. The amount of the revenue loss would depend on the number of entities that are subject to the GIT or CBT and participate as

donors, and the value of the drugs that they donate. Many of the entities that are likely to participate as donors are tax-exempt nonprofit organizations and so would not be affected by the tax credit provisions.

Finally, the bill could possibly lead to a reduction in costs for State programs that pay for prescription drugs, such as Medicaid and the Pharmaceutical Assistance for the Aged and Disabled (PAAD) program. (Most, but not all, State pharmaceutical assistance programs are operated by the Department of Human Services.) The bill allows each authorized drug donation program to establish its own eligibility criteria for individuals to receive donated drugs, but specifies that they must prioritize individuals who have low incomes, are uninsured or enrolled in a public health benefits program. To the extent that drugs are provided to public program participants, costs in those programs may be reduced. It is not clear whether such savings would exceed the combined total of drug donation program oversight expenditures and the revenue loss resulting from the tax credits.

Section: Human Services

*Analyst: David Drescher
Senior Fiscal Analyst*

*Approved: Frank W. Haines III
Legislative Budget and Finance Officer*

This legislative fiscal estimate has been produced by the Office of Legislative Services due to the failure of the Executive Branch to respond to our request for a fiscal note.

This fiscal estimate has been prepared pursuant to P.L.1980, c.67 (C.52:13B-6 et seq.).

ASSEMBLY, No. 1813

STATE OF NEW JERSEY 217th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2016 SESSION

Sponsored by:

Assemblyman HERB CONAWAY, JR.

District 7 (Burlington)

Assemblyman TIM EUSTACE

District 38 (Bergen and Passaic)

Assemblywoman ANGELICA M. JIMENEZ

District 32 (Bergen and Hudson)

Assemblyman THOMAS P. GIBLIN

District 34 (Essex and Passaic)

Co-Sponsored by:

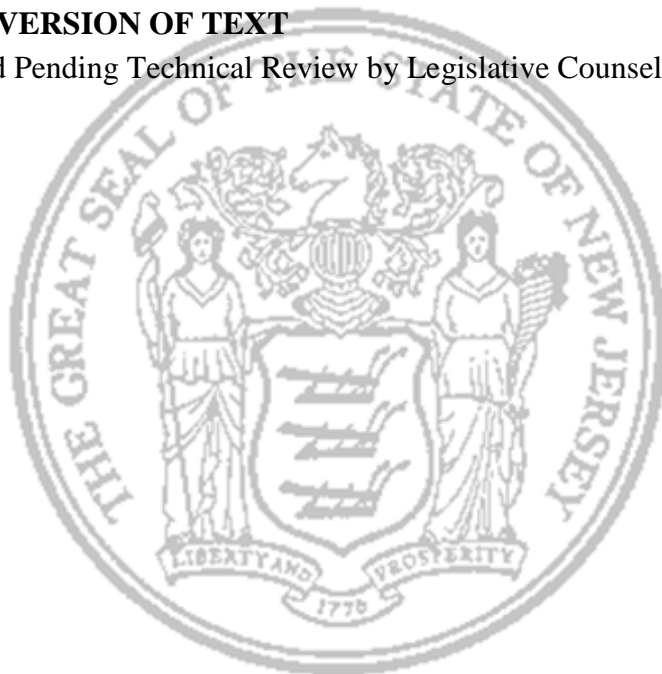
Assemblymen Prieto, Lagana, Chiaravalloti and Benson

SYNOPSIS

Establishes prescription drug donation repository program.

CURRENT VERSION OF TEXT

Introduced Pending Technical Review by Legislative Counsel.



(Sponsorship Updated As Of: 6/16/2017)

1 AN ACT establishing a prescription drug donation repository
2 program and supplementing Title 24 of the Revised Statutes.

3

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

6

7 1. The Legislature finds and declares that the health of low-
8 income persons in this State can be improved, and the cost to the
9 State of providing low-income persons with health care can be
10 reduced, by establishing a program that provides for the donation of
11 unused prescription drugs and supplies by persons, health care
12 facilities, and pharmacies to a central repository for redistribution to
13 medical facilities and pharmacies in order to re-dispense these
14 medications that would otherwise be destroyed.

15

16 2. As used in this act:

17 “Anti-rejection drug” means a prescription drug that suppresses
18 the immune system to prevent or reverse rejection of a transplanted
19 organ.

20 “Board” means the New Jersey State Board of Pharmacy.

21 “Cancer drug” means a prescription drug that is used to treat
22 cancer or the side effects of cancer, or the side effects of any
23 prescription drug that is used to treat cancer or the side effects of
24 cancer.

25 “Central repository” means a facility authorized by the State to
26 receive and repackage donated prescription drugs and supplies to
27 re-dispense to qualified individuals through authorized medical
28 facilities and pharmacies.

29 “Commissioner” means the Commissioner of Health.

30 “Controlled dangerous substance” means a controlled dangerous
31 substance as defined in N.J.S.2C:35-2.

32 “Department” means the Department of Health.

33 “Health care facility” means a health care facility licensed
34 pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.).

35 “Indigent” means that a person has an income that is below 200
36 percent of the federal poverty level.

37 “Medical facility” means a physician's office, hospital, outpatient
38 clinic, or nonprofit health clinic.

39 “Nonprofit health clinic” means a federally qualified health
40 center or rural health clinic as defined in 42 U.S.C. s.1396d(1), or a
41 nonprofit health clinic that provides medical care to patients who
42 are indigent, uninsured, or underinsured.

43 “Pharmacy” means a pharmacy located in this State that is
44 operating under a valid permit from the board.

45 “Prescriber” means a person authorized by the appropriate State
46 professional and occupational licensing board to prescribe
47 medication and devices as provided by law.

1 “Prescription drug” means any human drug required by federal
2 law or regulation to be dispensed only by prescription, including
3 dosage forms and active ingredients subject to section 503(b) of the
4 “Federal Food, Drug and Cosmetic Act” (21 U.S.C. s.353),
5 including cancer drugs and anti-rejection drugs, but does not
6 include controlled dangerous substances.

7 “Program” means the prescription drug donation repository
8 program established pursuant to this act.

9 “Repository” means the central repository established under the
10 program, which is designated to receive all donated prescription
11 drugs and supplies.

12 “Supplies” means supplies necessary to administer the
13 prescription drugs donated under the program.

14

15 3. a. The commissioner, in cooperation with the board, shall
16 establish and maintain a prescription drug donation repository
17 program in the department under which a person, health care
18 facility, or pharmacy may donate prescription drugs and supplies
19 for use by an individual who meets eligibility criteria specified by
20 regulation of the commissioner. All donated prescription drugs and
21 supplies shall be sent to the repository for processing in accordance
22 with regulations adopted by the commissioner. The department
23 may contract with a third party to implement and administer the
24 program.

25 b. Donations of prescription drugs and supplies under the
26 program may be made on the premises of a health care facility or
27 pharmacy that elects to participate in the program and meets the
28 requirements established by the commissioner.

29 c. The medical facility or pharmacy may charge an individual
30 who receives donated prescription drugs or supplies a handling fee
31 that shall not exceed an amount established by the commissioner.

32 d. Donated prescription drugs and supplies shall not be re-
33 dispensed without first being sent to the repository, subject to the
34 provisions of section 4 of this act, to be repackaged and
35 redistributed to participating medical facilities and pharmacies and,
36 subsequently, qualified individuals in accordance with the
37 provisions of this act.

38 e. The participation of any person, facility, or other entity in
39 the program shall be voluntary.

40

41 4. a. A prescription drug or supplies may be accepted and
42 dispensed under the program if all of the following conditions are
43 met:

44 (1) the prescription drug is in its original sealed and tamper-
45 evident packaging; however, a prescription drug in a single-unit
46 dose or blister pack with the outside packaging opened may be
47 accepted if the single-unit dose packaging remains intact;

- 1 (2) the prescription drug bears an expiration date that is more
2 than six months after the date that the prescription drug was
3 donated;
- 4 (3) the prescription drug or supplies are inspected by a
5 pharmacist employed by the repository before the prescription drug
6 or supplies are dispensed to a medical facility or pharmacy, in order
7 to determine that the prescription drug or supplies are not
8 adulterated or misbranded; and
- 9 (4) the prescription drug or supplies are prescribed by a
10 prescriber for use by an eligible individual and are dispensed by a
11 pharmacist.
- 12 b. A prescription drug or supplies donated pursuant to this act
13 shall not be resold by any person, facility, or other entity.
- 14 c. (1) If a person, health care facility, or pharmacy that donates
15 prescription drugs or supplies to the repository receives a notice
16 from a pharmacy or pharmaceutical manufacturer that a prescription
17 drug or supplies have been recalled, the person, health care facility,
18 or pharmacy donating the prescription drug or supplies shall inform
19 the repository of the recall. The repository shall notify all medical
20 facilities and pharmacies receiving the recalled drugs or supplies of
21 the recall.
- 22 (2) If a medical facility or pharmacy receives a recall
23 notification from a person, health care facility, pharmacy, or the
24 repository, the medical facility or pharmacy shall perform a uniform
25 destruction of all the recalled prescription drugs or supplies in the
26 medical facility or pharmacy.
- 27 d. A prescription drug dispensed through the program shall not
28 be eligible for reimbursement under any private health care
29 coverage or public health benefits program.
- 30 e. The commissioner shall prescribe by regulation such
31 requirements and other aspects of the program as are necessary to
32 effectuate the purposes of this act, including, but not limited to, the
33 following:
- 34 (1) requirements for medical facilities and pharmacies to accept
35 and dispense donated prescription drugs and supplies, including all
36 of the following:
- 37 (a) eligibility criteria for participation by medical facilities and
38 pharmacies;
- 39 (b) standards and procedures for accepting, safely storing, and
40 dispensing donated prescription drugs and supplies;
- 41 (c) standards and procedures for inspecting donated prescription
42 drugs to determine whether the prescription drugs are in their
43 original sealed and tamper-evident packaging, or, if the prescription
44 drugs are in single-unit doses or blister packs and the outside
45 packaging is opened, whether the single-unit dose packaging
46 remains intact; and

- 1 (d) standards and procedures for inspecting donated prescription
2 drugs and supplies to determine that the prescription drugs and
3 supplies are not adulterated or misbranded;
- 4 (2) eligibility criteria for individuals to receive donated
5 prescription drugs and supplies dispensed under the program, which
6 shall prioritize dispensing to individuals who are indigent or
7 uninsured, but may permit dispensing to other individuals if a need
8 for the donated prescription drugs and supplies is not identified
9 among indigent or uninsured persons;
- 10 (3) necessary forms for administration of the program, including
11 forms for use by individuals who donate, accept, distribute, or
12 dispense prescription drugs or supplies under the program;
- 13 (4) a means by which an individual who is eligible to receive
14 donated prescription drugs and supplies may indicate that
15 eligibility;
- 16 (5) the maximum handling fee that a medical facility or
17 pharmacy may charge for accepting, distributing, or dispensing
18 donated prescription drugs and supplies under the program;
- 19 (6) a list of prescription drugs that the program will not accept;
20 and
- 21 (7) criteria for any request for proposals that the department
22 may issue to engage a third party to implement and administer the
23 program.
24
- 25 5. a. A drug manufacturer acting reasonably and in good faith,
26 in accordance with the provisions of this act and as otherwise
27 required by law, shall be immune from civil or criminal liability for
28 any injury, death, or loss to a person or property related to the
29 donation, acceptance, or dispensing of a prescription drug
30 manufactured by the drug manufacturer that is donated pursuant to
31 this act, including liability for failure to transfer or communicate
32 product or consumer information or the expiration date of the
33 donated prescription drug.
- 34 b. A person other than a drug manufacturer, acting reasonably
35 and in good faith, in accordance with the provisions of this act and
36 within the scope of the program, shall be:
- 37 (1) immune from civil or criminal liability for any injury to, or
38 the death of, an individual to whom a donated prescription drug is
39 dispensed pursuant to this act, and
- 40 (2) exempt from disciplinary action related to the person's acts
41 or omissions with respect to the donation, acceptance, distribution,
42 or dispensing of a donated prescription drug pursuant to this act.
43
- 44 6. A prescription drug that can only be dispensed to a patient
45 registered with the manufacturer of that drug, in accordance with
46 requirements established by the federal Food and Drug
47 Administration, shall not be accepted or distributed under the
48 program.

1 7. The provisions of this act shall not be construed to restrict
2 the use of samples by a prescriber during the course of the
3 prescriber's duties at a medical facility or pharmacy.

4
5 8. The commissioner, in consultation with the Commissioner of
6 Human Services, shall annually issue a report to the Governor, and
7 to the Legislature pursuant to section 2 of P.L.1991, c.164
8 (C.52:14-19.1), which evaluates the effectiveness of the program
9 established pursuant to this act in providing prescription drugs and
10 supplies, and reducing the cost of providing health care, to low-
11 income persons in this State.

12
13 9. The commissioner, in consultation with the board and
14 pursuant to the "Administrative Procedure Act," P.L.1968, c.410
15 (C.52:14B-1 et seq.), shall adopt rules and regulations as necessary
16 to effectuate the purposes of this act.

17
18 10. This act shall take effect on the first day of the seventh
19 month next following the date of enactment, but the commissioner
20 may take such anticipatory administrative action in advance thereof
21 as shall be necessary for the implementation of this act.

22
23
24 STATEMENT

25
26 This bill establishes a prescription drug donation repository
27 program in the Department of Health (DOH).

28 This program will provide for the donation of unused
29 prescription drugs and supplies by persons, health care facilities,
30 and pharmacies to a central repository for redistribution to
31 authorized medical facilities and pharmacies in order to re-dispense
32 these medications, which would otherwise be destroyed, for use by
33 individuals who meet eligibility criteria specified by the
34 Commissioner of Health.

35 The commissioner, in cooperation with the State Board of
36 Pharmacy, is to establish and maintain the program, and DOH may
37 contract with a third party to implement and administer the
38 program.

39 Donations of prescription drugs and supplies under the program
40 may be made on the premises of a health care facility or pharmacy
41 that elects to participate in the program and meets the requirements
42 established by the commissioner.

43 The medical facility or pharmacy may charge an individual who
44 receives donated prescription drugs or supplies a handling fee that
45 is not to exceed an amount established by the commissioner.

46 The participation of any person, facility, or other entity in the
47 program is voluntary.

1 The bill stipulates that prescription drug or supplies may be
2 accepted and dispensed under the program if:

3 -- the prescription drug is in its original sealed and tamper-
4 evident packaging; however, a prescription drug in a single-unit
5 dose or blister pack with the outside packaging opened may be
6 accepted if the single-unit dose packaging remains intact;

7 -- the prescription drug bears an expiration date that is more than
8 six months after the date that the prescription drug was donated;

9 -- the prescription drug or supplies are inspected by a pharmacist
10 employed by the repository before the prescription drug or supplies
11 are dispensed to a medical facility or pharmacy, to determine that
12 the prescription drug or supplies are not adulterated or misbranded;
13 and

14 -- the prescription drug or supplies are prescribed by an
15 authorized prescriber for use by an eligible individual and are
16 dispensed by a pharmacist.

17 A prescription drug or supplies donated pursuant to this bill is
18 not to be resold by any person, facility, or other entity.

19 The bill provides that: a person, health care facility, or
20 pharmacy that donates prescription drugs or supplies to the
21 repository, and receives a notice from a pharmacy or
22 pharmaceutical manufacturer that a prescription drug or supplies
23 have been recalled, is to inform the repository of the recall; the
24 repository is to notify all medical facilities and pharmacies
25 receiving the recalled drugs or supplies of the recall; and the
26 medical facility or pharmacy that receives the recall notification is
27 to perform a uniform destruction of all the recalled prescription
28 drugs or supplies in the medical facility or pharmacy.

29 A prescription drug dispensed through the program will not be
30 eligible for reimbursement under any private health care coverage
31 or public health benefits program.

32 The bill directs the Commissioner of Health to prescribe by
33 regulation such requirements and other aspects of the program as
34 are necessary to effectuate the purposes of the bill, including, but
35 not limited to:

36 -- requirements for medical facilities and pharmacies to accept
37 and dispense donated prescription drugs and supplies;

38 -- eligibility criteria for individuals to receive donated
39 prescription drugs and supplies dispensed under the program, which
40 is to prioritize dispensing to individuals who are indigent or
41 uninsured;

42 -- necessary forms for administration of the program;

43 -- a means by which an individual who is eligible to receive
44 donated prescription drugs and supplies may indicate that
45 eligibility;

46 -- the maximum handling fee that a medical facility or pharmacy
47 may charge for accepting, distributing, or dispensing donated
48 prescription drugs and supplies under the program;

A1813 CONAWAY, EUSTACE

8

1 -- a list of prescription drugs that the program will not accept;
2 and

3 -- criteria for any request for proposals that DOH may issue to
4 engage a third party to implement and administer the program.

5 The bill further directs the Commissioner of Health, in
6 consultation with the Commissioner of Human Services, to annually
7 issue a report to the Governor and the Legislature that evaluates the
8 effectiveness of the prescription drug donation repository program
9 in providing prescription drugs and supplies, and reducing the cost
10 of providing health care, to low-income persons in this State.

11 The bill takes effect on the first day of the seventh month
12 following enactment, but authorizes the Commissioner of Health to
13 take prior administrative action as necessary for its implementation.

ASSEMBLY HEALTH AND SENIOR SERVICES COMMITTEE

STATEMENT TO

ASSEMBLY COMMITTEE SUBSTITUTE FOR ASSEMBLY, No. 1813

STATE OF NEW JERSEY

DATED: JUNE 19, 2017

The Assembly Health and Senior Services Committee reports favorably an Assembly Committee Substitute for Assembly Bill No. 1813.

This substitute bill allows private entities to voluntarily establish drug donation programs, pursuant to which health care facilities, pharmacies, pharmaceutical manufacturers, and similar entities will be permitted to donate over-the-counter drugs, prescription drugs, and administration supplies for use by people who are indigent, uninsured, or underinsured. An entity electing to establish a drug donation program may contract with a third-party intermediary to implement and administer the program.

Specifically, drug manufacturers, wholesalers, repackagers, returns processors, and third-party logistics providers, as well as health care facilities and pharmacies, will be permitted to donate unexpired over-the-counter and prescription medications that are contained in a sealed and tamper-evident packaging that remains intact. The substitute bill permits the donation of such over-the-counter and prescription medications as cancer drugs, anti-rejection drugs, and drugs that have been discontinued in a health care facility, but does not permit the donation of controlled dangerous substances, compounded drugs, or prescription drugs that can only be dispensed to a patient who is registered with the drug manufacturer. Donations may be accepted from donors located in another state, provided that the donation is permitted under the laws of that other state. The substitute bill further provides that drug donors are allowed a corporation business tax or gross income tax credit equal to the sum of: the cost of the over-the-counter drugs, prescription drugs, and administration supplies; and the verifiable cost incurred to make the donation of the drugs and supplies.

Under the substitute bill, drugs and supplies are to be donated to redistributors, including health care facilities, pharmacies, wholesalers, and return processors. Redistributors will be required to inspect the donated drugs to determine whether they have been adulterated or misbranded, and will be required to separate any donated drugs from other drug stocks. Redistributors are permitted to repackage donated drugs and administration supplies, or transfer donated drugs and administration supplies to another redistributor. Donated drugs and

administration supplies may be transferred to, and accepted from, redistributors located in another state, provided that the transfer is permitted under a drug donation program established in that other state.

Redistributors will be required to establish eligibility criteria for individuals to receive donated over-the-counter drugs and prescription drugs, with priority being granted to persons who are indigent, uninsured, or underinsured. Donated drugs are nonsalable and may not be resold by any person or entity, including a redistributor; however, redistributors will be authorized to charge a reasonable handling fee to individuals who are dispensed a donated drug. The handling fee may not exceed the actual validated cost of transporting, inspecting, repackaging, storing, and dispensing the over-the-counter drug or prescription drug, if the redistributor is for-profit.

The substitute bill specifies that donated prescription drugs may only be dispensed, pursuant to a valid prescription, by a pharmacist or other health care professional who is authorized by law to dispense prescription medications.

Whenever a donor receives a recall notice for a donated drug, the donor will be required to provide notice of the recall to any redistributor to whom it donated the recalled drug, unless the redistributor has provided the donor with a written statement attesting that the redistributor receives such recall notices through other means. In the same respect, if a redistributor has transferred a donated drug to another redistributor, and the drug is later recalled, the primary redistributor will be required to notify secondary redistributors of the recall, unless the subsequent redistributors have provided a written statement attesting that they receive recall notices through other means. Upon receiving notice of a recall, whether from a donor, a redistributor, or through other means, a redistributor will be required to perform a uniform destruction of all the recalled drugs in the redistributor's possession.

The substitute bill requires that, prior to the first donation from a new donor, a redistributor must verify and record the following as a donor record:

- (1) The donor meets the definition of donor;
- (2) The donor's name, address, phone number, and license number, if applicable;
- (3) Certification that the donor will not donate any controlled dangerous substances; and
- (4) Certification that, if applicable, the donor will remove or redact any patient names and prescription numbers on donated drugs or otherwise maintain patient confidentiality by executing a confidentiality agreement with the redistributor.

Any person or entity establishing a drug donation program under the substitute bill will be required to: (1) develop, implement, and make available to the Commissioner of Health, the Board of

Pharmacy, and members of the public, upon request, standards and procedures for meeting the requirements of the bill; and (2) develop, and make available, a list of over-the-counter drugs and prescription drugs that the program is seeking, accepting, or not accepting, including a list of over-the-counter drugs and prescription drugs that an individual redistributor participating in the program is seeking or will not accept.

Any person or entity that acts reasonably, and in good faith, in accordance with the provisions of the substitute bill, and within the scope of a drug donation program established thereunder, will be immune from civil and criminal liability for any injury to, or the death of, an individual to whom a donated drug is dispensed, and will similarly be exempt from disciplinary action related to any act or omission associated with an activity pursuant to the substitute bill. Drug manufacturers, wholesalers, or other entities participating in the supply chain of the donated drug or donated administration supplies will also be immune from civil or criminal liability for any injury, death, or loss related to any activity pursuant to the substitute bill. Redistributors will be immune from civil or criminal liability for dispensing a donated drug that has been recalled, but only if the redistributor was not notified of the recall.

Nothing in the substitute bill's provisions will be construed to restrict the use of drug samples by a licensed prescriber during the course of the prescriber's duties at a health care facility or pharmacy.