

SENATE, No. 1624

STATE OF NEW JERSEY 216th LEGISLATURE

INTRODUCED MARCH 17, 2014

Sponsored by:

Senator SHIRLEY K. TURNER

District 15 (Hunterdon and Mercer)

SYNOPSIS

Establishes prescription drug donation repository program.

CURRENT VERSION OF TEXT

As introduced.



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.

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

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

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

12 “Repository” means the central repository established under the
13 program, which is designated to receive all donated prescription
14 drugs and supplies.

15 “Supplies” means supplies necessary to administer the
16 prescription drugs donated under the program.

17

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

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

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

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

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

43

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

47 (1) the prescription drug is in its original sealed and tamper-
48 evident packaging; however, a prescription drug in a single-unit

1 dose or blister pack with the outside packaging opened may be
2 accepted if the single-unit dose packaging remains intact;

3 (2) the prescription drug bears an expiration date that is more
4 than six months after the date that the prescription drug was
5 donated;

6 (3) the prescription drug or supplies are inspected by a
7 pharmacist employed by the repository before the prescription drug
8 or supplies are dispensed to a medical facility or pharmacy, in order
9 to determine that the prescription drug or supplies are not
10 adulterated or misbranded; and

11 (4) the prescription drug or supplies are prescribed by a
12 prescriber for use by an eligible individual and are dispensed by a
13 pharmacist.

14 b. A prescription drug or supplies donated pursuant to this act
15 shall not be resold by any person, facility, or other entity.

16 c. (1) If a person, health care facility, or pharmacy that
17 donates prescription drugs or supplies to the repository receives a
18 notice from a pharmacy or pharmaceutical manufacturer that a
19 prescription drug or supplies have been recalled, the person, health
20 care facility, or pharmacy donating the prescription drug or supplies
21 shall inform the repository of the recall. The repository shall notify
22 all medical facilities and pharmacies receiving the recalled drugs or
23 supplies of the recall.

24 (2) If a medical facility or pharmacy receives a recall
25 notification from a person, health care facility, pharmacy, or the
26 repository, the medical facility or pharmacy shall perform a uniform
27 destruction of all the recalled prescription drugs or supplies in the
28 medical facility or pharmacy.

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

32 e. The commissioner shall prescribe by regulation such
33 requirements and other aspects of the program as are necessary to
34 effectuate the purposes of this act, including, but not limited to, the
35 following:

36 (1) requirements for medical facilities and pharmacies to accept
37 and dispense donated prescription drugs and supplies, including all
38 of the following:

39 (a) eligibility criteria for participation by medical facilities and
40 pharmacies;

41 (b) standards and procedures for accepting, safely storing, and
42 dispensing donated prescription drugs and supplies;

43 (c) standards and procedures for inspecting donated prescription
44 drugs to determine whether the prescription drugs are in their
45 original sealed and tamper-evident packaging, or, if the prescription
46 drugs are in single-unit doses or blister packs and the outside
47 packaging is opened, whether the single-unit dose packaging
48 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 c. A person, health care facility, or pharmacy that dispenses
44 donated prescription drugs or supplies that have been recalled shall
45 be immune from civil or criminal liability if the person, health care
46 facility, or pharmacy was not notified of the recall by the
47 repository.

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

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

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

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

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

14 -- the prescription drug or supplies are inspected by a pharmacist
15 employed by the repository before the prescription drug or supplies
16 are dispensed to a medical facility or pharmacy, to determine that
17 the prescription drug or supplies are not adulterated or misbranded;
18 and

19 -- the prescription drug or supplies are prescribed by an
20 authorized prescriber for use by an eligible individual and are
21 dispensed by a pharmacist.

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

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

34 A prescription drug dispensed through the program will not be
35 eligible for reimbursement under any private health care coverage
36 or public health benefits program.

37 The bill directs the Commissioner of health to prescribe by
38 regulation such requirements and other aspects of the program as
39 are necessary to effectuate the purposes of the bill, including, but
40 not limited to:

41 -- requirements for medical facilities and pharmacies to accept
42 and dispense donated prescription drugs and supplies;

43 -- eligibility criteria for individuals to receive donated
44 prescription drugs and supplies dispensed under the program, which
45 is to prioritize dispensing to individuals who are indigent or
46 uninsured;

47 -- necessary forms for administration of the program;

1 -- a means by which an individual who is eligible to receive
2 donated prescription drugs and supplies may indicate that
3 eligibility;
4 -- the maximum handling fee that a medical facility or pharmacy
5 may charge for accepting, distributing, or dispensing donated
6 prescription drugs and supplies under the program;
7 -- a list of prescription drugs that the program will not accept;
8 and
9 -- criteria for any request for proposals that DOH may issue to
10 engage a third party to implement and administer the program.
11 The bill further directs the Commissioner of Health, in
12 consultation with the Commissioner of Human Services, to annually
13 issue a report to the Governor and the Legislature that evaluates the
14 effectiveness of the program in providing prescription drugs and
15 supplies, and reducing the cost of providing health care, to low-
16 income persons in this State.
17 The bill takes effect on the first day of the seventh month
18 following enactment, but authorizes the Commissioner of Health to
19 take prior administrative action as necessary.