CHAPTER 254
(CORRECTED COPY)

AN ACT authorizing the establishment of drug donation programs, and supplementing Title 24 and Title 54 of the Revised Statutes and Title 54A of the New Jersey Statutes.

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

C.24:6M-1 Findings, declarations relative to drug donation.

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

C.24:6M-2 Definitions relative to drug donation.

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

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

"Anti-rejection drug" means an over-the-counter drug or prescription drug that suppresses the immune system to prevent or reverse the rejection of a transplanted organ.

"Board" means the State Board of Pharmacy.

"Cancer drug" means a prescription drug that is used to treat cancer or the side effects of cancer, or that is used to treat the side effects of any other prescription drug that is used to treat cancer or the side effects of cancer.

"Commissioner" means the Commissioner of Health.

"Compounded drug" means a sterile or nonsterile compounded formulation for dispensing or administration pursuant to a prescription, that is prepared for a patient with needs that cannot be met by a commercially available prescription drug.

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

"Correctional facility" means a county or state correctional facility, county juvenile detention facility, secure juvenile facility, federal prison, or other comparable facility.

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

"Donor" means a drug manufacturer, wholesaler, repackager, returns processor, third-party logistics provider, health care facility, correctional facility, pharmacy, or any other person or entity that is properly licensed and authorized to possess prescription drugs, and which elects to donate over-the-counter drugs, prescription drugs, or administration supplies pursuant to this act.

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

"Grooming and hygiene product" is soap or cleaning solution, shampoo, toothpaste, mouthwash, anti-perspirant, or sun tan lotion or screen, regardless of whether the item meets the definition of "over-the-counter drug."

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

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

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

“Over-the-counter-drug" means a drug that contains a label that meets the requirements of 21 CFR 201.66, including (1) a "Drug Facts" panel; or (2) a statement of the "active ingredient" or "active ingredients" with a list of those ingredients contained in the compound, substance, or preparation. "Over-the-counter drug" does not include a grooming and hygiene product.

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

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

“Redistributor” means a health care facility, pharmacy, wholesaler, returns processor, or any other person or entity that is properly licensed and authorized to dispense over-the-counter drugs and prescription drugs, and which agrees to accept, repackage, transfer to other redistributors, and, if otherwise authorized by law, dispense donated drugs and administration supplies to eligible individuals pursuant to this act. “Redistributor” includes an out-of-State redistributor.

“Returns processor” shall mean the same as that term is defined by 21 U.S.C. s.360eee (18). “Returns processor” includes a reverse distributor.

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

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

“Transaction date” means the date at which ownership of the drug was donated or transferred between two participants of the program as established by contract or other arrangement. If no such contract or arrangement exists, the transaction date shall be the date the drug was accepted into inventory by the redistributor.

C.24:6M-3 Establishment, maintenance of drug donation program.

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

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

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

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

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

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

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

(5) a means by which an individual may indicate that the individual is eligible to receive donated drugs and administration supplies under the program, which may comprise in part or whole of self-certification;

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

d. Donated over-the-counter drugs, prescription drugs, and administration supplies may be transferred from one redistributor to another redistributor in this State, and may be transferred to or from a redistributor in another state, provided that such transfer is permitted under the laws of that other state. The donation, transfer, or facilitation of donations and transfers of over-the-counter drugs or prescription drugs pursuant to this subsection shall not be deemed to constitute wholesale distribution and shall not require licensing as a wholesaler.

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

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

f. A common carrier or contract carrier may be used to transport donated over-the-counter drugs, prescription drugs, and administration supplies, in accordance with manufacturer recommendations, including but not limited to, from a donor to a redistributor,

from a redistributor to another redistributor, from a redistributor to a donor, or from a redistributor to an eligible patient.

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

C.24:6M-4 Conditions relative to program.

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

(1) the donated drugs are contained in a sealed and tamper-evident package that remains intact;

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

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

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

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

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

(7) the dispensed drugs and administration supplies have an expiration or beyond use date brought forward from the donated drug that will not expire before the use by the patient based on the prescribing practitioner's directions for use or, for over-the-counter drugs, on the package’s label; and

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

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

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

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

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

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

e. (1) A redistributor’s receipt of reimbursement or payment from another redistributor, a governmental agency, a pharmacy benefit manager, a pharmacy services administration organization, or a health care coverage program under this section, including a usual and

customary charge, shall not be deemed to constitute the resale of prescription drugs for the purposes of this act, or for the purposes of any other law or regulation.

(2) A redistributor may also charge a handling fee to an eligible individual who is dispensed a donated drug pursuant to this act, provided that, if the redistributor is for-profit, the fee does not exceed the reasonable costs of procuring, transporting, inspecting, repackaging, storing, and dispensing the donated drug. A redistributor that charges a handling fee pursuant to this paragraph shall maintain a record validating the charge, and shall make that record available to the department upon request.

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

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

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

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

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

(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.

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

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

j. All donated drugs and administration supplies received but not yet accepted into inventory shall be kept in a separate designated area. Prior to or upon accepting a donation or transfer into inventory, a redistributor shall maintain a written or electronic inventory of the donation, consisting of the transaction date, the name, strength, and quantity of each accepted drug and the name and quantity of any accepted administration supplies, and the name, address, and phone number of the donor. This record shall not be required if the two parties

are under common ownership or common control. No other record of donation shall be required.

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

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

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

C.24:6M-5 Immunity from liability.

5. a. Any donor, redistributor, third-party intermediary, common carrier, contract carrier, governmental agency, including but not limited to the Department of Health and the board, pharmacy benefit manager, pharmacy services administration organization, health care coverage program, or other entity or person, including but not limited to volunteers, employees, officers, directors, owners, partners, managers, and members, who acts reasonably and in good faith, within the scope of a drug donation program, and in accordance with the provisions of this act, shall be: (1) immune from civil or criminal liability for any injury, death, or loss suffered by a person who is dispensed a donated drug or donated administration supplies under this act; and (2) exempt from any professional disciplinary action stemming from any act or omission associated with any activity pursuant to this act, including but not limited to, the donation, acceptance, repackaging, transportation, transfer, or dispensing of a donated drug or donated administration supplies.

b. A drug manufacturer, wholesaler, or other entity participating in the supply chain of the donated drug or donated administration supplies who acts reasonably and in good faith, in accordance with the provisions of this act, and as otherwise required by law, shall be immune from civil or criminal liability for any injury, death, or loss to a person or property stemming from any act or omission in association with any activity pursuant to this act including but not limited to the donation, acceptance, repackaging, transportation, transfer, or dispensing of an over-the-counter drug or prescription drug that is manufactured or distributed by the drug manufacturer, wholesaler, or other entity and donated pursuant to this act, including any liability resulting from a failure to transfer or communicate product or consumer information or the expiration date of the donated drug.

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

C.24:6M-6 Construction of act.

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

C.24:6M-7 Rules, regulations.

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

C.24:6M-8 Tax credit for donor.

8. a. For privilege periods beginning on or after the effective date of P.L.2017, c.254 (C.26:6M-1 et seq.), a taxpayer that is a donor shall be allowed a credit against the tax imposed pursuant to section 5 of P.L.1945, c.162 (C.54:10A-5), in an amount equal to the sum of: the cost to the taxpayer of the over-the-counter drugs, prescription drugs, and administration supplies as determined pursuant to 26 U.S.C. s.170(e)(3)(A); and the verifiable cost to the taxpayer to make the donation of the over-the-counter drugs, prescription drugs, and administration supplies to a redistributor during the taxable year in accordance with a drug donation program established pursuant to the provisions of P.L.2017, c.254 (C.26:6M-1 et seq.), provided that:

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

(2) the over-the-counter drugs, prescription drugs, or administration supplies were donated to, and accepted by, a redistributor in accordance with the provisions of P.L.2017, c.254 (C.26:6M-1 et seq.); and

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

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

c. As used in this section: "donor," "over-the-counter drugs," "prescription drugs," "administration supplies," "redistributor," "returns processor," and "drug donation program" shall mean the same as those terms are defined by section 2 of P.L.2017, c.254 (C.26:6M-2).

C.24:6M-9 Tax credit for donor.

9. a. For taxable years beginning on or after the effective date of P.L.2017, c.254 (C.26:6M-1 et seq.), a taxpayer that is a donor shall be allowed a credit against the tax otherwise due under the "New Jersey Gross Income Tax Act," N.J.S.54A:1-1 et seq., in an amount equal to the sum of: the cost to the taxpayer of the over-the-counter drugs, prescription drugs, and administration supplies as determined pursuant to 26 U.S.C. s.170(e)(3)(A); and the verifiable cost to the taxpayer to make the donation of the over-the-counter drugs, prescription drugs, and administration supplies to a redistributor during the taxable year in accordance with a drug donation program established pursuant to the provisions of P.L.2017, c.254 (C.26:6M-1 et seq.), provided that:

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

(2) the over-the-counter drugs, prescription drugs, or administration supplies were donated to, and accepted by, a redistributor in accordance with the provisions of P.L.2017, c.254 (C.26:6M-1 et seq.); and

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

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

(2) A business entity that is classified as a partnership for federal income tax purposes shall not be allowed a credit directly under the gross income tax, but the amount of credit of a taxpayer in respect of a distributive share of partnership income shall be determined by allocating to the taxpayer that proportion of the credit acquired by the partnership that is equal to the taxpayer's share, whether or not distributed, of the total distributive income or gain of the partnership for its taxable year ending within or with the taxpayer's taxable year. A New Jersey S corporation shall not be allowed a credit directly under the gross income tax, but the amount of credit of a taxpayer in respect of a pro rata share of S Corporation income shall be determined by allocating to the taxpayer that proportion of the credit acquired by the New Jersey S Corporation that is equal to the taxpayer's share, whether or not distributed, of the total pro rata share of S Corporation income of the New Jersey S Corporation for its privilege period ending within or with the taxpayer's taxable year.

c. As used in this section: "donor," "over-the-counter drugs," "prescription drugs," "administration supplies," "redistributor," "returns processor," and "drug donation program" shall mean the same as those terms are defined by section 2 of P.L.2017, c.254 (C.26:6M-2).

10. This act shall take effect on the 180th day next following the date of enactment, except that the Commissioner of Health, the Director of the State Board of Pharmacy, and the Director of the Division of Taxation in the Department of the Treasury may take such

anticipatory administrative action in advance thereof as shall be necessary for the implementation of this act.

Approved January 8, 2018.