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HEALTH

HEALTH SYSTEMS BRANCH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE PROGRAM

Drug Donation Programs

Proposed New Rules: N.J.A.C. 8:32

Authorized By: Judith M. Persichilli, R.N., B.S.N., M.A., Commissioner, Department of Health (with the approval of the New Jersey State Board of Pharmacy), in consultation with the State Board of Pharmacy and the Division of Taxation.

Authority: N.J.S.A. 24:6M-7.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2023-072.

Submit electronic comments to http://www.nj.gov/health/legal/ecomments.shtml, or written comments to the address below, by October 6, 2023, to:

Joy L. Lindo, Director

Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

PO Box 360

Trenton, NJ 08625-0360

The agency proposal follows:

Summary

The Department of Health ("Department" or "DOH") proposes new rules regarding the process for authorizing drug donation program(s). On January 8, 2018, Governor Philip D. Murphy signed P.L. 2017, c. 254, into law which required the Commissioner of the Department (Commissioner), the State Board of Pharmacy (Board), and the Director of the Division of Taxation in the Department of the Treasury to take administrative action to authorize one or more private entities to establish and maintain a drug donation program that would permit donors to donate 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.

The proposed new rules would set forth standards that an applicant seeking to establish and maintain a drug donation program must meet. The applicant would be required to submit a drug donation program proposal that includes a description of the entity, including its history, mission, ownership structure, staffing, and any other characteristics or relevant facts that demonstrate the organization's ability to establish a drug donation program appropriately and safely. The applicant must also provide policies and procedures for accepting, transporting, safely storing, and dispensing donated drugs and administration supplies.

Donors would be allowed a credit against tax otherwise due pursuant to the New Jersey Gross Income Tax Act, N.J.S.A. 54A:1-1 et seq., or the New Jersey Corporation Business Tax, N.J.S.A. 54:10A-1 et seq.

A summary of the proposed new rules follows.

Proposed new Subchapter 1 addresses general provisions.

Proposed new N.J.A.C. 8:32-1.1 sets forth the scope and purpose of the rules, which establishes a new drug donation program in the Department of Health, in coordination with the Board of Pharmacy and the Department of the Treasury, Division of Taxation. Proposed new N.J.A.C. 8:32-1.2 provides the definitions of words and terms that are used throughout the chapter.

Proposed new Subchapter 2 addresses the application process to establish a drug donation program. Proposed new N.J.A.C. 8:32-2.1 outlines the process to apply to establish and maintain a drug donation program.

Proposed new Subchapter 3 addresses the establishment and maintenance of a drug donation program. Proposed new N.J.A.C. 8:32-3.1 establishes the requirements for donation, facilitation, and transfer of over-the-counter drugs and prescriptions for drug donation programs.

Proposed new Subchapter 4 establishes standards for the handling of donated drugs. Proposed new N.J.A.C. 8:32-4.1 requires drug donation programs follow certain conditions for the acceptance of donated drugs, packaging, transfers, recall of drugs, and storage of drugs and supplies.

Proposed new Subchapter 5 addresses the renewal process for a drug donation program. Proposed new N.J.A.C. 8:32-5.1 creates a renewal process.

Proposed new Subchapter 6 addresses the process for drug donors to receive tax credits. Proposed new N.J.A.C. 8:32-6.1 sets forth the process for receipt of a tax

credit by a donor during the privilege period. Proposed new N.J.A.C. 8:32-6.2 sets the process for acquisition of a tax credit for donors during a taxable year.

Proposed new Subchapter 7 addresses the transfer of ownership process that drug donation programs are to follow. Proposed new N.J.A.C. 8:32-7.1 sets forth the process for transfer of ownership and submission of an application to the Department and the Board for review.

Proposed new Subchapter 8 addresses possible enforcement actions. Proposed new N.J.A.C. 8:32-8.1 establishes the process for the suspension, revocation, or denial of authorization of a drug donation program. Proposed new N.J.A.C. 8:32-8.2 establishes the hearing process, if requested by the drug donation program, regarding enforcement actions. Proposed new N.J.A.C. 8:32-8.3 allows drug donation programs to request settlement of enforcement actions in lieu of an administrative hearing. Proposed new Subchapter 9 addresses immunity from criminal and civil liability. Proposed new N.J.A.C. 8:32-9.1 provides information regarding immunity from liability for drug donation programs and exemption from professional liability actions.

As the Department provides a 60-day comment period for this notice of proposal, pursuant to N.J.A.C. 1:30-3.3(a)5, this notice is excepted from the rulemaking calendar requirement.

Social Impact

The proposed new rules are expected to have a positive social impact by allowing for the donation and redistribution of unused drugs and drug administration supplies to those persons who are most in need, while also allowing the donor an opportunity for a tax credit.

Economic Impact

There are costs involved with implementing a drug donation program. Entities that operate a drug donation program have staffing, storage, recordkeeping requirements, and other economic costs and potential compliance requirements that may bring about monetary penalties and potential suspensions. Although there are costs involved, there are the benefits associated with receipt of tax credits for the facilitation of drug donations to low-income persons.

Federal Standards Statement

These new rules are not proposed pursuant to the authority of, or in order to implement, comply with, or participate in any program established pursuant to Federal law. In addition, the new rules are not proposed pursuant to the authority of a State statute that incorporates or refers to Federal law or Federal standards. Therefore, no Federal standards analysis is required.

Jobs Impact

The Department believes that the proposed new rules may increase the number of jobs in New Jersey, because drug donations programs may need staffing. Therefore, there is a positive impact.

Agriculture Industry Impact

The Department believes the proposed new rules will have no impact upon the agriculture industry in New Jersey.

Regulatory Flexibility Analysis

The proposed new rules would impose requirements on drug donation programs. Some programs may be considered small businesses, as the term is defined in the

Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The proposed new rules do not impose application fees, and the creation of a drug donation program or participation in one is completely voluntary. The proposed new rules do have potential compliance requirements, such as documentation and recordkeeping. Drug donation programs are required to document:

1. Transaction date the drug is donated;

2. Any charges imposed by the distributor for accepting the drugs or supplies;

3. The name, strength, quantity, and cost to the taxpayer of each accepted drug;

4. The name, quantity, and cost to the taxpayer of any accepted administration supplies;

5. The name, Social Security or Federal tax identification number, address, and phone number of the donor; and

6. The total calculated tax credit. The drug donation program's calculation and certification of the total amount of tax credit to be allowed to the donor, based on the donor's cost of the accepted drugs and administration supplies plus any charges that the drug donation program imposes for accepting the donation.

It is not possible to calculate the potential costs of creating a drug donation program, because the proposed rules foster a great deal of flexibility which can result in a wide array of drug donation programs. Some proposed programs may serve a large number of donors and recipients and others may be very narrowly constructed. No lesser requirements or exceptions can be provided based upon business size in the interest of public health, quality of care, and safety.

Housing Affordability Impact Analysis

The proposed new rules will have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the proposed new rules would evoke a change in the average costs associated with housing because the proposed new rules concern the provision of services by drug donation programs in the State.

Smart Growth Development Impact Analysis

The proposed new rules will have an insignificant impact on smart growth and there is an extreme unlikelihood that the proposed new rules would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, pursuant to the State Development and Redevelopment Plan in New Jersey because the proposed new rules concern the provision of services by drug donation programs.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has determined that the proposed new rules would not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults or juveniles in the State. Accordingly, no further analysis is required.

Full text of the proposed new rules follows:

CHAPTER 32

DRUG DONATION PROGRAMS

SUBCHAPTER 1. GENERAL PROVISIONS

8:32-1.1 Purpose and scope

(a) The purpose of this chapter is to implement the requirements at N.J.S.A. 24:6M-1 et seq., which requires the Department of Health (Department), in cooperation with the State Board of Pharmacy (Board), to review and authorize proposals for the creation of drug donation programs in the State.

(b) The provisions of this chapter shall apply to any entity or entities seeking authorization to operate a drug donation program.

8:32-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"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 the Department of Health.

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

"Controlled dangerous substance" means the same as that term is defined at N.J.S.A. 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.

“Department” means the New Jersey Department of Health.

“Director” means the Director of the New Jersey Division of Taxation.

“Diversion” means the transfer of a donated drug, over-the-counter drug, or administration supply, to a non-eligible individual, without the approval of the Department.

“Division” means the New Jersey Division of Taxation.

"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 chapter.

"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 chapter.

"Drug donation program" means a program, established pursuant to the provisions of this chapter and in accordance with N.J.S.A. 24:6M-1 et seq., to accept 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.

“Eligible individual” means an individual or individuals who are indigent, uninsured, or enrolled in a public health benefits program, or 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.

"Grooming and hygiene product" means soap or cleaning solution, shampoo, toothpaste, mouthwash, anti-perspirant, suntan lotion or screen, or other hygiene product 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 pursuant to 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 (N.J.S.A. 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 pursuant to the laws of the state in which the person or entity is located.

"Over-the-counter drug" means a drug that includes a label that meets the requirements at 21 CFR 201.66, as amended and supplemented, 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 substances or compounded drugs.

“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 chapter. “Redistributor” includes an out-of-State redistributor.

“Returns processor” shall mean the same as that term is defined at 21 U.S.C. § 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 a 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 chapter, 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.

SUBCHAPTER 2. APPLYING FOR AUTHORIZATION TO ESTABLISH AND MAINTAIN A DRUG DONATION PROGRAM

8:32-2.1 Applying for authorization

(a) An entity may at any time apply with the Department for authorization to establish and maintain a drug donation program.

(b) To apply, the entity must complete the Drug Donation Application (DDP-1) which is available on the Department’s website at https://healthapps.state.nj.us/forms/ and submit it with a program proposal to DrugDonation@doh.nj.gov.

(c) A program proposal should include the following information:

1. A description of the entity, including its history, mission, ownership structure, size, staff, and any characteristics that demonstrate the organization's ability to effectively establish a drug donation program;

2. Standards and procedures for accepting, transporting, safely storing, and dispensing donated drugs and/or administration supplies;

3. 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;

4. Standards and procedures for inspecting donated drugs to ensure that the drugs are not adulterated or misbranded;

5. Standards and procedures for preventing diversion;

6. Standards and procedures for calculating donor tax credits;

7. Eligibility criteria for individuals to receive donated drugs and administration supplies dispensed pursuant to the drug donation program, which ensures those receiving donated drugs are indigent, uninsured, or enrolled in a public health benefits program, or 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;

8. A list of over-the-counter drugs and prescription drugs that the program is seeking, willing to accept, and not willing to accept; and

9. A detailed list of all individuals that will come into contact with donated drugs, and the oversight they are under.

1. The Department, in consultation with the Board, will review the program proposal and may either:

    2. Approve the program proposal and grant authorization;

    3. Request amendments as a condition of authorization; or

    4. Reject the program proposal and not grant authorization.

(e) If the Department approves the program proposal and grants authorization, the entity must strictly abide by the approved standards and procedures in the approved program proposal.

(f) If the entity wishes to amend the approved standards and procedures, it must first notify the Department of the proposed amendments through email at DrugDonation@doh.nj.gov, and receive approval to make the desired amendments.

(g) If the name, address, or contact information of the entity changes, the organization must submit the updated information to the Department through email at DrugDonation@doh.nj.gov, not later than 30 days after the change occurs.

(h) If an entity intends to close or cease operations, the entity must first report the closure or cessation of operations to the Department through email at DrugDonation@doh.nj.gov, no later than 30 days prior to said closure or cessation and must submit and receive approval for a plan to maintain records as required pursuant to this chapter, as well as plans for destroying any excess inventory of donated drugs.

(i) An entity must submit a new program proposal and get approval to resume its drug donation program if it has ceased operations.

SUBCHAPTER 3. MAINTENANCE OF DRUG DONATION PROGRAM

8:32-3.1 Maintenance

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

(b) Donated over-the-counter drugs, prescription drugs, and administration supplies may be transferred:

1. From one redistributor to another redistributor in this State; and

2. To or from a redistributor in another state, provided that such transfer is permitted pursuant to the laws of that other state.

(c) The donation, transfer, or facilitation of donations and transfers of over-the-counter drugs or prescription drugs pursuant to this chapter shall not be deemed to constitute wholesale distribution and shall not require licensing as a wholesaler.

(d) The following are eligible for donation:

1. Any over-the-counter drugs;

2. Prescription drugs;

3. Administration supplies, including, but not limited to, over-the-counter drugs; and

4. Prescription drugs, and administration supplies that are discontinued in a health care facility, and that would otherwise be destroyed.

(e) A prescription drug that can only be dispensed to an individual 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 individual.

(g) The participation of any person, facility, or other entity in a drug donation program pursuant to this chapter shall be voluntary.

SUBCHAPTER 4. DRUG DONATION PROGRAM CONDITIONS

8:32-4.1 Conditions

(a) Donated drugs and administration supplies may be accepted, transferred, and dispensed by a redistributor, 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 who is authorized by law to dispense over-the-counter drugs and prescription drugs 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 who is authorized by law to dispense over-the-counter drugs and prescription drugs

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 individual information on the donated container redacted or removed and destroyed;

6. The dispensed drugs and administration supplies are properly labeled, in accordance with the rules of the Board;

7. The dispensed drugs and administration supplies have a beyond use date brought forward from the donated drug that will not expire before the use by the individual 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 pursuant to the laws of the other state.

(c) 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.

(d) Repackaged drugs shall be labeled with the drug name, strength, and beyond use date, and shall be kept in a separate designated area until inspected and

initialed by a pharmacist or other health care professional who is authorized by law to dispense over-the-counter drugs and prescription drugs.

(e) If multiple packaged donated drugs with varied beyond use dates are repackaged together, the soonest beyond use date shall be used.

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

(g) 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 pursuant to this section, including a usual and customary charge, shall not be deemed to constitute the resale of prescription drugs for the purposes of this chapter, or for the purposes of any other law or rule.

(h) A redistributor may also charge a handling fee to an eligible individual who is dispensed a donated drug pursuant to this chapter, 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 subsection shall maintain a record validating the charge and shall make that record available to the Department upon request.

(i) 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.

(j) If a redistributor receives notice of a recall pursuant to (i) above, 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.

(k) 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.

(l) 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 pursuant to this chapter;

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;

4. Certification that the donor owns the drugs and it is not under legal or has a contractual obligation to return the donated drugs to another party;

5. Certification that the donor has stored the drugs, in accordance with manufacturer's recommendations or instructions; and

6. Certification that, if applicable, the donor will remove or redact any names of individuals and/or prescription numbers on donated drugs or otherwise maintain confidentiality by executing a confidentiality agreement with the redistributor.

(m) A drug manufacturer, repackager, pharmacy, or wholesaler other than a returns processor participating in the drug donation program, shall comply with the requirements at 21 U.S.C. §§ 360eee-1 through 360eee-4, relating to drug supply chain security.

(n) If a redistributor does not accept donated drugs and administration supplies, the redistributor shall dispose of those items by returning the drugs or supplies to the donor, destroying the drugs or supplies by an incinerator or other lawful method, or transferring them to a returns processor. A redistributor shall maintain a record of disposed drugs and administration supplies, which 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.

(o) 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, proof of the donor's cost of the donated drugs, and the name, address, Social Security or Federal tax ID number, 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.

(p) Once the redistributor examines the drugs and formally accepts them, the drug donation program will provide a receipt detailing the transaction to the donor. The redistributor must retain an identical copy of the receipt for a period of four years. The Division may request a copy during this time. After the retention period of four years, the receipt may be destroyed. The receipt shall include the following information:

1. Transaction date;

2. Any charges imposed by the distributor for accepting the drugs or supplies;

3. The name, strength, quantity, and cost to the taxpayer of each accepted drug;

4. The name, quantity, and cost to the taxpayer of any accepted administration supplies;

5. The name, Social Security or Federal tax ID number, address, and phone number of the donor; and

6. The total calculated tax credit. The drug donation program's calculation and certification of the total amount of tax credit to be allowed to the donor, based on the donor's cost of the accepted drugs and administration supplies, plus any charges that the drug donation program imposes for accepting the donation.

(q) An authorized recipient shall maintain the donated drugs pursuant to adequate storage conditions, including proper lighting, ventilation, and temperature control, as recommended by the drug manufacturer. If storage conditions are not specified by the drug manufacturer, the prescription drug or chemical shall be maintained

according to the parameters set forth in the Drug Substance Monographs and Excipients of the United States Pharmacopeia/National Formulary, 2022 edition, incorporated herein by reference, as amended and supplemented, and which is available for purchase at the United States Pharmacopeia/National Formulary website at www.usp.org. Where no specific directions or limitations are provided in the packaging and storage section of individual monographs or in the manufacturer specifications, the conditions of storage shall include storage at a temperature maintained thermostatically between 20 and 25 degrees Celsius (68 and 77 degrees Fahrenheit), protection from moisture, and, where necessary, protection from light.

(r) All records required pursuant to this section 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 pursuant to this rule if it allows for such information to be readily retrievable. An identifier shall not be used on drug labels when dispensing or administering a drug.

(s) 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 drug label, in accordance with Board rules.

SUBCHAPTER 5. AUTHORIZATION RENEWAL

8:32-5.1 Authorization renewal

(a) An entity's authorization is valid for three years and is subject to renewal.

(b) Authorized entities applying for renewal shall submit to the Department a completed Drug Donation Renewal Application DDP-1 available on the Department's forms website at https://healthapps.state.nj.us/forms/ and submit it with a copy of the existing policies and procedures to DrugDonation@doh.nj.gov.

(c) The Department shall renew the authorization of the entity, provided:

1. The entity accurately completes a renewal application;

2. The entity's authorization has not been suspended or revoked previously;

3. There has been no material change in the circumstances upon which the Department based its previous authorization;

4. There are no concerns regarding the safety or effectiveness of the drug donation program; and

5. The entity intends to maintain the approved existing policies and procedures or receives authorization to alter them.

SUBCHAPTER 6. TAX CREDIT FOR DONOR

8:32-6.1 Corporation business tax credit for donor privilege period

(a) For privilege periods beginning on or after July 7, 2018, a taxpayer that is a donor to an approved drug donation program shall be allowed a credit against the tax imposed pursuant to N.J.S.A. 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. § 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 at N.J.S.A. 24:6M-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 at N.J.S.A. 24:6M-1 et seq.; and

3. The redistributor, which processed the donated drug, complies with all recordkeeping requirements for non-saleable returns to a returns processor pursuant to 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 of Taxation. The amount of the credit applied pursuant to 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 at N.J.S.A. 54:10A-5.e. The amount of the credit allowable pursuant to 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 pursuant to the corporation business tax.

(c) The donor shall apply for the credit when filing their taxes, by utilizing Form 326 and attaching a copy of their receipt (see N.J.A.C. 8:32-4.1(p)). The taxpayer's use of the tax credit shall be limited pursuant to (a) or (b) above, as applicable.

8:32-6.2 Gross income tax credit for donor in taxable year

(a) For taxable years beginning on or after July 7, 2018, a taxpayer that is a donor to an approved drug donation program shall be allowed a credit against the tax otherwise due pursuant to the New Jersey Gross Income Tax Act, N.J.S.A. 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. § 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 at N.J.S.A. 24:6M-1 et seq., provided that the:

1. Donor paid for, owned, or was responsible for the over-the-counter drugs, prescription drugs, or administration supplies;

2. Over-the-counter drugs, prescription drugs, or administration supplies were donated to, and accepted by, a redistributor in accordance with the provisions at N.J.S.A. 24:6M-1 et seq.; and

3. Redistributor, which processed the donated drug, complies with all recordkeeping requirements for non-saleable returns to a returns processor pursuant to Federal law.

(b) The amount of the credit applied pursuant to 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 pursuant to this section that 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.

1. A business entity that is classified as a partnership for Federal income tax purposes shall not be allowed a credit directly, pursuant to 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 pursuant to 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) The donor shall apply for the credit by sending a copy of their receipt (see N.J.A.C. 8:32-4.1(p)) and tax return to:

New Jersey Division of Taxation

Gross Income Tax Audit Branch

PO Box 288

Trenton, NJ 08695-0288

Attention: Drug Donation Program Tax Credit

(d) The taxpayer’s use of the tax credit shall be limited pursuant to N.J.A.C. 8:32-6.2(a) or (b), as applicable.

SUBCHAPTER 7. TRANSFER OF OWNERSHIP OF DRUG DONATION PROGRAM

8:32-7.1 Transfer of ownership

(a) Prior to transferring ownership of a drug donation program, the prospective new owner shall submit an application to the Department of Health. The application shall include the following items:

1. A cover letter stating the applicant's intent to purchase the drug donation program, and identification of the drug donation program by name, address, and county.

2. A description of the proposed transaction, including:

i. Identification of the current owners of the drug donation program;

ii. Identification of 100 percent of the proposed new owners, including the names and addresses of all principals (that is, individuals and/or entities with a 10 percent or more equitable interest or with managerial control); and

iii. If applicable, a copy of an organizational chart, including parent corporations and wholly owned subsidiaries;

3. A copy of the agreement of sale and, if applicable, a copy of any lease and/or management agreements; and

4. A copy of the existing approved policies and procedures with a signed affidavit detailing the new owner agrees to fully adhere to the policies and procedures and any applicable rules; or a new program proposal that differs from the existing and approved policies and procedures.

(b) Approval of a transfer of ownership is contingent upon a review of the applicant, the record of the drug donation program, and approval of any changes to the existing policies and procedures.

SUBCHAPTER 8. ENFORCEMENT ACTIONS

8:32-8.1 Suspension, revocation, or denial of authorization; appeal

(a) The Department may deny an authorization request or authorization renewal application of an entity if the applicant does not meet the requirements set forth at N.J.S.A. 24:6M-1 et seq., if the applicant has deviated from its approved standards or procedures, if the applicant fails to provide any information or documentation requested

by the Department or fails to comply with any requests or instructions from the Department, or if the applicant violates any other applicable rules or statutes.

(b) The Department may suspend, summarily suspend, and/or revoke the authorization of an entity if the entity fails to comply with the applicable provisions at N.J.S.A. 24:6M-1 et seq., its approved standards and procedures, or any other applicable rules or statutes, or if the applicant fails to provide any information or documentation requested by the Department or fails to comply with any requests or instructions from the Department.

(c) If an entity fails to get authorization from the Department as prescribed by these rules, or continues to operate after its authorization is suspended or revoked, then the Department may take the following actions against said organization:

1. The Department may issue an order requiring the operation of an unauthorized, suspended, or revoked drug donation program to cease and desist.

2. The Department may also impose other enforcement actions pursuant to these rules for operation of an unauthorized, suspended, or revoked drug donation program, or for failing to abide by the approved policies and procedures.

3. The Department may maintain an action in the New Jersey Superior Court to enjoin any entity from operating an unauthorized drug donation program or after the suspension or revocation of authorization pursuant to this section.

4. The Department may implement a plan of correction if the entity fails to abide by applicable provisions at N.J.S.A. 24:6M-1 et seq., its approved standards and procedures, or any other applicable rules or statutes, or if the applicant fails to provide any information or documentation requested by the Department or fails to comply with

any requests or instructions from the Department. Failure to implement and abide by the plan of correction may lead to suspension or revocation of authorization.

5. The Department of Health, Board of Pharmacy, and Division of Taxation reserve the right to survey, inspect, or audit the entity and its program including any records, inventory, or real property.

8:32-8.2 Hearings on enforcement actions

(a) Notice of a proposed enforcement action shall be afforded to the entity.

(b) The entity shall notify the Department of its intent to request a hearing regarding the proposed enforcement action in the manner specified in the notice required pursuant to (a) above within 30 days of its receipt.

(c) The Department shall transmit the hearing request to the Office of Administrative Law.

(d) Hearings shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

8:32-8.3 Settlement of enforcement actions

(a) The drug donation entity may request that the proposed enforcement action be settled in lieu of conducting an administrative hearing.

(b) If the Department and the drug donation entity agree on the terms of a settlement, a written agreement specifying these terms shall be executed.

(c) If a drug donation entity fails to meet the conditions of the settlement, then the Department may immediately impose the original enforcement action.

SUBCHAPTER 9. IMMUNITY FROM LIABILITY

8:32-9.1 Immunity from liability

(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 of Pharmacy, 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 chapter, 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 pursuant to this chapter; and

2. Exempt from any professional disciplinary action stemming from any act or omission associated with any activity pursuant to this chapter, 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 chapter, 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 chapter 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 beyond use 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 has 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.